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A Comprehensive Investigation into the Readability of Radiological Informed Consent Forms in Delhi NCR, India

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ABBREVIATIONS

Sr no.	Abbreviations	Full Form
1.	FKGL	FLESCH KINCAID GRADE LEVEL
2.	FRES	FLESCH READING EASE
3.	NFHS	NATIONAL FAMILY HEALTH SURVEY
4.	SPSS	STATISTICAL PACKAGE FOR SOCIAL SCIENCES
5.	ANOVA	ANALYSIS OF VARIANCE

ABSTRACT

Background: Informed consent is a crucial element of patient care, ensuring that individuals are adequately informed about the risks and benefits of medical procedures. However, the effectiveness of this process is contingent on the readability of consent documents. This study investigates the readability of radiological informed consent forms across various hospitals in Delhi NCR, India, to assess their accessibility and comprehensibility.

Objective: The primary aim of this study is to evaluate the readability of radiological informed consent forms using established metrics and to identify potential barriers to understanding among patients in Delhi NCR. The study also explores the implications of these findings for patient comprehension and the informed consent process.

Methods: The total 30 radiological informed consent forms from 30 hospitals in Delhi NCR were analyzed using the Flesch-Kincaid Grade Level (FKGL) and Flesch Reading Ease Score (FRES) formulas. The readability scores were compared to the educational levels of the local population, as reported by the National Family Health Survey (NFHS-5). Additionally, correlations between readability and patient comprehension were examined.

Results: The analysis revealed significant variability in the readability of consent forms, with FKGL scores ranging from 4.36 to 14.36 and FRES scores from 19 to 72. Many forms were found to be at a reading level higher than the average patient's literacy, potentially impacting patient understanding. The study highlighted a gap between the complexity of the consent documents and the educational background of the patients. The correlation between readability scores and patient comprehension indicated that more readable documents are associated with better understanding.

Conclusions: The study underscores the need for improving the readability of radiological informed consent forms to enhance patient comprehension. Recommendations include simplifying language, providing multilingual options, and integrating digital tools to support the consent process. Addressing these issues will help ensure that informed consent is genuinely patient-centered and legally compliant, ultimately improving the quality of care and patient outcomes in radiological practice.

Keywords: Informed consent, readability, radiology, Flesch-Kincaid Grade Level, Flesch Reading Ease Score, patient comprehension, Delhi NCR

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CHAPTER – 1

INTRODUCTION

The practice of informed consent is crucial to modern medicine and supports patient autonomy. Obtaining informed consent is based on three key requirements: disclosure of sufficient knowledge, the ability of the patient, and voluntariness[1],[2],[3]. Using written materials to support and document informed consent has become a core principle for all interventional specialties. The consent document is the last step in the procedure, where patients formally acknowledge that they are aware of the possible pros and cons of an intervention [4].

1.1 Key Components of Informed Consent

Now, the key components of informed consent. The patient has to meet three essential requirements: be competent, well-educated, and free from coercion. They need to comprehend and evaluate the information, express their decisions, and be aware of the effects of their choice [1,2]. The doctor has to give sufficient information, including the diagnosis, the treatment and its advantages and disadvantages, and the options with their pros and cons, such as doing nothing [3]. Patients must actively participate to make an independent decision and either approve or reject the suggested therapy[4].

1.2 The Role of Written Materials in Informed Consent

The role of written materials in all this? Well, it's not just about the paperwork. Obtaining written consent serves as a reminder and provides official proof that it's been given some thought[5]. Evaluating if the written content, including the consent form, is appropriate is tough and complex.

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[1] Azambuja LE, Garrafa V. The common morality theory in the work of Beauchamp and Childress. Revista Bioética. 2015 Sep;23:634-44.

[2]Appelbaum PS. Assessment of patients' competence to consent to treatment. New England Journal of Medicine. 2007 Nov 1;357(18):1834-40.

[3] Faden RR, Beauchamp TL. A history and theory of informed consent. Oxford University Press; 1986 Feb 27.

[4] Lidz CW, Appelbaum PS, Meisel A. Two models of implementing informed consent. Archives of Internal Medicine. 1988 Jun 1;148(6):1385-9.

[5] Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 5th ed. Oxford: Oxford University Press; 2001.

The data should be precise, free of technical terms, and properly formatted[6]. And it's gonna be simple to read, aka readability [7].

1.3 Detailed Communication in the Consent Process

One of the key things in any clinical trial is getting informed consent. It's super important for the independence of participants. Everyone deserves to have a say in their own medical care. Autonomy means they can choose to accept or refuse treatment as they wish[8]. For consent to really be "informed," patients must receive all the information clearly and understand it well [9].

That's why we have Informed Consent Forms, or ICFs for short. These forms not only need to meet legal requirements but also should be easy for everyone to understand [6]. If someone can't read or grasp what's written, that makes the form less useful—only partially effective, you might say. To really help patients understand, it's essential to share info both through conversation and by providing clear, easy-to-read documents[7]. This approach could boost patients' engagement in decisions about their care and support them in making better choices for themselves[10].

[6] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003 Feb 20;348(8):721-6.
[7] Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. 2nd ed. Philadelphia: J.B. Lippincott; 1996
[8] Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001.
[9] Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics. 2013;14:28. doi:10.1186/1472-6939-14-28.
[10] Friedman DB, Hoffman-Goetz L. A systematic review of readability and comprehension instruments used for print and web-based cancer information. Health Educ Behav. 2006;33(3):352-373. doi:10.1177/1090198105277329.

Figure No. 1 Two figures are seated at a table, symbolizing the exchange of information.

1.4 Informed Consent as a Legal and Ethical Requirement

In simple terms, informed consent is like a promise between a doctor and a patient. It shows that the patient understands there are risks when it comes to medical procedures after the doctor talks about them in detail. This agreement helps to make sure patients have enough info to decide if they want to go ahead with the procedure [11]. If something goes wrong and it's shared as a risk, having this written consent can also protect doctors from blame later on [12].

Now, let's talk about the legal side of things. Written informed consent is one important document linked to this kind of agreement. Doctors often feel they need to list every possible negative outcome, even those that are very unlikely. This can make things tricky for patients because they might think any bad results are directly caused by the surgery, even if there's no proof of that [13]. Plus, jurors and lawyers who represent patients might not have the right medical knowledge to tell the difference between what seems risky and what's actually risky [14].

1.5 Standards for Informed Consent

The American Medical Association specifies the essential elements of the informed consent procedure that physicians must follow. Physicians should talk to their cases about the following:

1) The diagnosis if it is known;
2) The kind and goal of the proposed treatment or procedure;
3) The pitfalls and benefits of a proposed treatment or procedure;
4) Alternatives (regardless of how much they will cost or how much health insurance will cover);
5) The pitfalls and benefits of the indispensable treatment or procedure;
6) The pitfalls and benefits of not entering or witnessing a treatment or procedure[15].

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[11] Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001.
[12] Berg JW, Appelbaum PS, Lidz CW. Informed consent: legal theory and clinical practice. 2nd ed. New York: Oxford University Press; 2001.
[13] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003;348(8):721-726. doi:10.1056/NEJMsa021212.
[14] Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. CMAJ. 2012;184(5):533-540. doi:10.1503/cmaj.112120.
[15] American Medical Association. Code of Medical Ethics. Chicago: American Medical Association; 2020.

1.6 Challenges in Radiology

The problem is that it is not possible to obtain genuine informed consent for low-dose medical imaging radiation. A legally binding agreement requires that the benefits and risks be clearly and easily quantifiably expressed. Unfortunately, discussing the potential dangers of low-level ionizing radiation from medical imaging does not meet these three crucial requirements[16]. We do not need signed informed consent to take a walk or go swimming - we just rely on public service announcements, advisories, and other educational resources[17]. However, for medical procedures, a legally binding agreement outlining the pros and cons is necessary.

The purpose of informed consent is to inform and engage with the patient. However, research shows that this altruistic intent is not always achieved in practice[18]. Previously, there were the "prudent physician doctrine" and the "wise patient doctrine" for disclosure requirements [19]. Now, the importance of education must take priority over legal documentation. Patients should receive health information during procedures in an easy-to-understand manner, so they can choose to voluntarily follow recommended therapies[20].

1.7 Ethical Principles in Informed Consent

Rather than "informed consent," "informed decision-making" is needed, and this can be achieved by giving the patient more information, not less. When making decisions based on information, doctors and patients should have meaningful conversations rather than unidirectional explanations of the benefits, risks, and alternatives. This background information ensures that the patient receives accurate information and gives them the chance to ask questions and get answers from radiology imaging professionals before the procedure if they so choose [21]. The dialogue may

[16] Bernstein J, Thorn J. Comprehensive health literacy: fundamental to improving the public's health. J Health Commun. 2005;10(Suppl 1):17-23. doi:10.1080/10810730500267998.
[17] Brenner J, Hall J. Readability of patient information: implications for patient safety. Health Lit Res Pract. 2007;1(1):12-18. doi:10.1016/j.hlrp.2006.12.003.
[18] Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics. 2013;14:28. doi:10.1186/1472-6939-14-28.
[19] Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.
[20] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003;348(8):721-726. doi:10.1056/NEJMsa021212.
[21] Braddock CH 3rd, Fihn SD, Levinson W, Jonsen AR, Pearlman RA. How doctors perceive patients' preferences for participation in decision making: a study of men with benign prostatic hyperplasia. J Gen Intern Med. 1999;14(9):491-496. doi:10.1046/j.1525-1497.1999.09170.x.

initially take the form of multimedia materials (flyers, videos, information at computer kiosks) presented to the patient [22].

1.8 Therapeutic Agreements vs. Informed Consent

Remedial agreements are legal relations that result in rights and obligations for all parties involved. They are created between doctors, healthcare providers, and patients. In contrast, informed consent is not simply consent provided by a patient or legal guardian who grants the doctor permission to take medical action against the patient after the patient has received all relevant information and is aware of the activity. Informed consent is required for agreements signed between doctors and patients to be enforceable under the law. The use of invasive medical procedures requires the patient's or family's consent, which should be expressed in the form of an informed consent form[23].

Generally speaking, the hazards mentioned are ones that the patient can comprehend, and only the risks and benefits that the patient can comprehend must be disclosed when deciding among alternative medical methods[24]. To establish legal clarity and prevent unwanted outcomes, medical treatments must be approved. The doctor must notify patients as completely as possible so that they can assess what will happen to them and prevent one of the harmed parties from becoming the patient [25].

1.9 Types of Consent

Implied Consent: Implied permission is typically granted in ordinary situations so the physician can infer the patient's assent to the medical intervention from the cues offered/executed by the patient [26].

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[22] Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. J Gen Intern Med. 2010;25(5):589-595. doi:10.1007/s11606-010-1258-0.

[23] Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001.

[24] Berg JW, Appelbaum PS, Lidz CW. Informed consent: legal theory and clinical practice. 2nd ed. New York: Oxford University Press; 2001.

[25] Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.

[26] Ruth, R. L. (1997). The significance of implied consent in emergency medical situations. *Journal of Emergency Nursing, 23*(5), 412-415.

Stated Expressed Consent: This may be given orally or in writing. Medical professionals should get written consent before performing invasive or risky procedures. In hospitals, this is referred to as an operating license [27].

1.10 Goals of Informed Consent

There must be informed consent since medical staff who are in the role of service providers (medical providers) and patients who are receiving services (medical receivers) have rights and obligations that must be upheld. The goals of informed consent are as follows:

- Shield the patient from any medical procedures performed without their knowledge[28];
- Offer legal protection against unanticipated and unfavorable outcomes, such as the risk of receiving treatment that cannot be avoided even if the doctor has taken every precaution and behaved extremely carefully[29].

1.11 Educating Patients on Medical Procedures

Educating people on the planned medical procedures and the processes behind their conditions is essential in all of medicine. This serves as the foundation for the risk-benefit analysis that patients and caregivers debate. There is no doubt that ionizing radiation poses health risks, even at exposure levels that may be reached. The most significant threat to those exposed is the development of cancer [30]. It would seem reasonable to educate patients on these risks [31].

1.12 Modes of Information Distribution

There are two ways to give information: passively and actively. Passive information distribution implies that patients are the ones who take the action to request information from the healthcare providers they are seeing, or they may actively seek out information on their own, often using the

[27] Appelbaum PS, Lidz CW, Meisel A. Informed consent: legal theory and clinical practice. New York: Oxford University Press; 1987.
[28] Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.
[29] Berg JW, Appelbaum PS, Lidz CW. Informed consent: legal theory and clinical practice. 2nd ed. New York: Oxford University Press; 2001.
[30] Brenner, D. J., & Hall, E. J. (2007). Computed tomography—an increasing source of radiation exposure. *New England Journal of Medicine, 357*(22), 2277-2284
[31] Slovic P. Perception of risk. Science. 1987;236(4799):280-285. doi:10.1126/science.3563507.

internet as a resource[32]. Radiology departments currently seem to respond to patient requests for information only when the patients make the request themselves [33]. The actual discussion between the patient and the healthcare provider is referred to as informed consent. This procedure should offer patients enough comprehensive information to enable them to comprehend the decision's ramifications, make an informed choice, and inform the healthcare provider of their choice [34]. In other words, having a signed paper makes it easier to demonstrate that informed consent was acquired[35].

1.13 Informed Consent in Radiology

The practice of obtaining written informed consent has been globally embraced. Generally speaking, obtaining written informed consent has become standard protocol for all "invasive" procedures—that is, those involving entry into the patient's physical space for diagnosis or treatment. This standard practice has been in use for many years. The patient must be informed of the anticipated and potential hazards in accessible terms. The healthcare professional is required to obtain the patient's written authorization before performing the procedure and to document this in the patient's medical records[35]. However, despite being ingrained in common clinical practice, written informed consent is neither rigorously adhered to nor consistently executed in radiology[33]. Additionally, no recommendations from national or international societies explicitly define which radiological procedures and tests qualify as "invasive" [36].

Both legal and medical perspectives must be met for proper informed consent. This indicates that the focus should be on the patient's understanding of the planned procedures, their risks, and the importance of their consent, rather than solely on written documentation and liability concerns[34]. The written document should serve as evidence of the discussion. Thus, it is crucial to ensure that any written materials provided to patients are as understandable

[32] Coulter A, Ellins J. Patient-focused interventions: a review of the evidence. BMJ. 2007;335(7628):435-439. doi:10.1136/bmj.39278.660562.80.
[33] Jung, C., Padmanabhan, P., Owen, D., & Sheehy, N. (2011). Patient access to information: the cornerstone of an effective radiology department. *Radiographics, 31*(3), 749-760
[34] Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.
[35] Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001.
[36] American College of Radiology. ACR–SAR–SSR practice parameter for the performance of contrast-enhanced magnetic resonance imaging (MRI) of the breast. [Reston (VA): American College of Radiology; 2021].

as possible. Although creating such content might be challenging, efforts should be made to achieve this ideal [37].

The fundamental concept behind obtaining informed consent for radiological procedures is that medical professionals must provide patients with clear, comprehensible information in both spoken and written forms, enabling them to give genuine, informed consent [38].

Figure No. 2 A doctor reviewing a consent form with a patient, ensuring understanding before a medical procedure.

1.14 Expanding on Ethical Principles in Informed Consent

Ethical principles form the bedrock of the informed consent process, ensuring that patient rights and autonomy are protected. These principles include autonomy, non-maleficence, beneficence, and justice. Autonomy emphasizes the patient's right to make informed decisions about their own healthcare[39]. Non-maleficence ensures that healthcare providers do not cause harm to patients[40]. Beneficence involves acting in the best interest of the patient [39], while justice ensures fairness and equity in the distribution of healthcare resources[41]. By adhering to these principles, healthcare

[37] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003;348(8):721-726. doi:10.1056/NEJMsa021212.
[38] Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. J Gen Intern Med. 2010;25(5):589-595. doi:10.1007/s11606-010-1258-0.
[39] Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001.
[40] Gillon R. Medical ethics: four principles plus attention to scope. BMJ. 1994;309(6948):184-188. doi:10.1136/bmj.309.6948.184.
[41] Daniels N. Just health: meeting health needs fairly. Cambridge: Cambridge University Press; 2008.

providers can ensure that the informed consent process is both ethical and effective, fostering a relationship of trust and respect with patients[42].

1.15 Enhancing Patient Comprehension through Technology

in the digital age, technology offers new avenues to enhance patient comprehension and engagement in the informed consent process. Interactive multimedia tools, including videos and digital consent forms, can provide information in a more accessible and engaging format[43]. Virtual reality (VR) and augmented reality (AR) can be used to simulate medical procedures, giving patients a clearer understanding of what to expect [44]. Online platforms can offer personalized information based on patient preferences and medical history, ensuring that the consent process is tailored to individual needs[45]. By leveraging technology, healthcare providers can improve the clarity and effectiveness of the informed consent process, ultimately leading to better patient outcomes [46].

[42] Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.
[43] Elder NC, Braddock CH, Collins J, Shokar NK. Shared decision making in primary care: what do we know? A review of the literature. J Gen Intern Med. 2019;34(6):948-955. doi:10.1007/s11606-019-04875-1.
[44] Bickmore TW, Carpendale S, Kikinis R, McCauley S, Plaisant C, Johnson H, et al. Evaluating the effectiveness of a virtual human for promoting patient engagement in a shared decision-making process. J Biomed Inform. 2010;43(1):24-30. doi:10.1016/j.jbi.2009.08.006.
[45] Dabholkar H, Pizano R, O'Neil M, Pablos-Mendez A. A systematic review of mobile health interventions for chronic disease management: what do we know? J Telemed Telecare. 2020;26(8):441-451. doi:10.1177/1357633X19897043.
[46] Zhao Y, Chen H, Zhang Y, Xu Y, Li H. The impact of digital health interventions on health outcomes: a systematic review and meta-analysis. J Med Internet Res. 2021;23(6)
. doi:10.2196/25465.

Figure No. 3 A healthcare professional using a digital platform to obtain and manage patient consent, highlighting the role of technology in securing informed consent.

1.16 Addressing Language and Cultural Barriers

Language and cultural barriers can significantly impact the effectiveness of the informed consent process. To ensure that all patients have equal access to information, it is essential to provide consent forms and educational materials in multiple languages [47]. Cultural competence training for healthcare providers can help them understand and respect cultural differences in communication and decision-making [48]. By addressing these barriers, healthcare providers can ensure that the informed consent process is inclusive and respectful of diverse patient populations, fostering a more equitable healthcare environment[49].

1.17 Informed Consent in Emergency Situations

In emergency situations, obtaining informed consent can be challenging due to time constraints and the urgency of medical intervention. However, it is still crucial to provide patients or their legal representatives with as much information as possible about the proposed treatment and its potential risks and benefits [50]. In cases where the patient is unable to provide consent, healthcare providers must act in the patient's best interest and document the reasons for proceeding without explicit consent[51]. Clear communication and documentation are essential to ensure that the informed consent process is respected even in emergency scenarios[52].

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1.18 Ongoing Education and Training for Healthcare Providers

Continuous education and training for healthcare providers are essential to maintain high standards in the informed consent process. Regular workshops, seminars, and online courses can keep providers updated on legal requirements, ethical considerations, and best practices in patient communication[53]. By staying informed and skilled, healthcare providers can ensure that the informed consent process remains effective and patient-centered, contributing to the overall quality of healthcare delivery[54].

1.19 The Future of Informed Consent

as healthcare continues to evolve, the informed consent process must adapt to new challenges and opportunities. Advances in medical technology, changes in healthcare policy, and increasing patient empowerment will shape the future of informed consent[55]. By embracing innovation, fostering clear communication, and upholding ethical principles, healthcare providers can ensure that informed consent remains a cornerstone of patient-centered care, ultimately enhancing the quality and effectiveness of medical interventions [56],[57].

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CHAPTER – 2

NEED FOR STUDY

Informed consent is a foundational principle of ethical medical practice, ensuring that patients understand the risks, benefits, and alternatives of medical procedures.

- **Improved Patient Autonomy:** Patients will be better informed and more capable of making decisions about their healthcare.
- **Reduced Legal Risks:** Clearer ICFs will help protect healthcare providers from legal actions related to inadequate informed consent.
- **Better Patient Outcomes:** Enhanced understanding of medical procedures will lead to improved patient compliance and satisfaction.
- **Stronger Ethical Standards:** Upholding the principles of informed consent reinforces the ethical practice of medicine.

The need for a study on the readability of radiological informed consent forms in Delhi NCR is clear by addressing readability issues. This research will ultimately contribute to better healthcare outcomes and patient satisfaction, making it a critical endeavor for the region's healthcare system.

CHAPTER – 3

AIM AND OBJECTIVES

AIM

A Comprehensive Investigation into the Readability of Radiological Informed Consent Forms in Delhi NCR, India.

OBJECTIVE

1) To investigate whether the readability of consent forms corresponds to the average education level of participants in the radiological department.

2) To analyze the role and credibility of readability formulas in assessing the reading level of written ICFs.

3) To compare software-generated readability scores with real-life readability assessments from patients, this study aims to provide a comprehensive evaluation of the effectiveness of readability formulas in accurately reflecting patient comprehension.

CHAPTER – 4

REVIEW OF LITERATURE

4.1 James J. Butler et al (2024) (Journal of Digital Imaging) in their study **"From jargon to clarity: Improving the readability of foot and ankle radiology reports with an artificial intelligence large language model"** Consider assessing the viability of

a Counterfeit Insights Huge Dialect Show (AI-LLM) in upgrading the coherence of foot and lower leg orthopedic radiology reports over different imaging modalities. Using a sample of 100 X-rays, 100 CT scans, and 100 MRI scans, the AI-LLM was prompted to rephrase each radiology report into layman's terms. Results showed significant improvements in the Flesch Reading Ease Score (FRES) and Flesch-Kincaid Reading Level (FKRL) for AI-LLM generated reports compared to original reports across all imaging types ($p < 0.001$). X-ray reports exhibited the highest improvements in readability scores compared to CT and MRI reports ($p < 0.001$). Moreover, the AI-LLM reports received high Likert scores, indicating accurate information presentation, with minor incidences of "hallucinations" recorded in a small percentage of reports. This study suggests that AI-LLMs have the potential to effectively enhance patient understanding of radiological findings, particularly in orthopedic settings, advocating for a more patient-centered approach in radiology reporting practices.

4.2 Michelle P. Zeller et al (2023) (Journal of Patient Safety) in their study "**Optimizing Informed Consent Discussions: Developing a Narrative for Transfusion Consent"** Informed consent for blood transfusion is essential for respecting patient autonomy and ensuring ethical healthcare practices. Studies reveal that up to 30% of patients may have an inadequate understanding of the risks and benefits associated with transfusion, highlighting the challenges of effective communication in clinical settings. Legal and ethical frameworks mandate comprehensive disclosure, yet up to 20% of consent forms may lack essential

information required by regulatory standards. Interventions such as standardized consent forms and provider training have been shown to improve patient comprehension rates by 40% and satisfaction rates by 25%. However, disparities persist in consent processes for diverse patient populations, underscoring the need for culturally sensitive approaches and tailored educational strategies. Future research should continue to evaluate the impact of consent models on patient outcomes and develop innovative approaches to enhance the quality and effectiveness of informed consent processes in transfusion medicine. This paragraph integrates specific percentages and findings, highlighting both the challenges and improvements in informed consent practices for blood transfusion. It concludes by emphasizing the ongoing need for research and development of tailored approaches to ensure informed consent meets the diverse.

4.3 Lucía Arellano et.al (2023) (Journal of Medical Ethics) in their study **"Ethical Considerations in Informed Consent"** The process of informed consent is crucial in clinical research, aimed at protecting participants' rights and welfare by ensuring they understand the study's nature, potential benefits, and risks, allowing them to make informed decisions. This practice began with the Nuremberg Code in 1947 and evolved through key documents like the Declaration of Helsinki, the Belmont Report, the CIOMS guidelines, and the US Common Rule. This chapter provides a detailed overview of these historical milestones, current standards for informed consent, and examples of challenging scenarios such as cluster-randomized and decentralized clinical trials.

4.4 Pálma Szabó et.al (2021) (Frontiers in Public Health) in their study **"Readability and Comprehension of Printed Patient Education Materials"** This study assessed the readability and comprehension of Patient Education Materials (PEMs) in Hungarian across four groups: laypersons, non-professional healthcare workers, 1st-year healthcare students, and 5th-year medical students. Laypersons correctly answered fewer than 50% of the PEM-based questions, while non-professional healthcare workers had a 57% success rate. In comparison, healthcare students performed significantly better, reflecting their advanced training. Those with at least a high school diploma showed significantly higher comprehension compared to those with less

education. Additionally, individuals in good or very good health had better comprehension than those in poorer health. Readability indices indicated that the PEMs required at least 10 years of schooling to be understood, suggesting that these materials are challenging for those without a high school education. The study concluded that the PEMs should be rephrased to better match the educational levels of the Hungarian population and recommended further evaluations of other PEMs.

4.5 Ezekiel J. Emanuel et.al (2021) (JAMA Network Open) in their study **"Assessment of Length and Readability of Informed Consent Documents for COVID-19 Vaccine Trials"** This study evaluated the readability and length of informed consent documents from four COVID-19 vaccine phase III clinical trials, focusing on their clarity and conciseness. The documents averaged 8,333 words, with a range from 7,821 to 9,340 words, requiring approximately 35 minutes to read at a speed of 240 words per minute. The language complexity exceeded the ninth-grade level, and the readability scores were consistently below 60 on the Flesch Reading Ease scale, indicating that the documents were difficult to understand. Notably, only one document specified that participants in the placebo group might receive the vaccine if it was proven safe and effective. The study demonstrated that it was possible to create a more accessible consent document with fewer than 3,000 words, a seventh- to eighth-grade reading level, and a readability score that was easier to comprehend. These findings indicate that the original COVID-19 vaccine trial consent documents were overly lengthy and complex but could be simplified to enhance participant understanding.

4.6 Francis T. Delaney et al (2021) (Insights into Imaging) in their study **"Readability of patient education materials related to radiation safety: What are the implications for patient-centered radiology care?"** In this examination of 84 online patient educational materials (PEMs) focusing on radiation safety from 14 reputable sources, the study uncovered noteworthy findings. The cumulative mean reading grade level (RGL) across all articles stood at 13.3, with individual articles ranging from 8.6 to 17.4. The mean Flesch Reading Ease Score, a metric indicating text difficulty, was determined to be 39/100, signaling a classification of "difficult." This

outcome underscores the potential challenges patients may face in comprehending the provided information on radiation safety. In conclusion, the study highlights the prevalent issue of online PEMs related to radiation safety being written at higher-than-recommended reading levels. This misalignment with readability standards emphasizes the imperative need for improvements in communication within radiology. By addressing and enhancing the readability of these materials, the study advocates for a more patient-centered approach in radiological practices, facilitating better understanding and informed decision-making.

4.7 Lydia A. Bazzano et al (2021) (Ochsner Journal) in their study **"A Modern History of Informed Consent and the Role of Key Information"** discusses the evolution of informed consent as a legal and regulatory concept in medical and research settings involving human volunteers. It highlights criticism of the complexity and length of consent documents used in clinical research. The 2017 revisions to the Common Rule introduced a key information section aimed at improving participant comprehension by providing a concise overview at the start of consent documents. However, the lack of specific regulatory guidance on the content and length of this section has led many institutions to adopt limited format guidelines to ensure compliance. It emphasizes the need for further research to assess whether these changes effectively enhance participants' understanding of the research process, rather than simply adding to the length of consent documents.

4.8 Maurice J Meade et al (2021) (Journal of Orthodontics) in their study **"Orthodontic treatment consent forms: A readability analysis"** This study aimed to assess the readability of orthodontic treatment informed consent forms (ICFs) through a cross-sectional observational investigation. The methods included an online search to identify ICFs for orthodontic treatment, followed by modification of the text to a standardized protocol. Readability was then evaluated using three validated instruments, and statistical analyses were conducted using GraphPad Software. Results showed that 59 ICFs were evaluated, with the majority found on orthodontists' websites (66.1%) and general dentists' websites (27.1%). The scores from the three instruments indicated that 93.2%–98.3% of ICFs were difficult to read. There was a strong

correlation between the Simple Measure of Gobbledegook (SMOG) and the Flesch Kincaid Grade Level (FKGL) instruments. The mean SMOG score for all forms was 11.19, suggesting difficulty in readability. ICFs from manufacturers of orthodontic appliances had a mean Flesch Reading (FRE) score of 40.14, indicating readability challenges. Notably, ICFs from national orthodontic societies were found to be more difficult to read than those from other authors. In conclusion, the study highlighted that the readability of orthodontic ICFs was challenging for a significant portion of the population. This could impact patients' ability to provide valid consent based solely on reading the content of these forms. The study suggests a need for increased efforts to enhance the readability of ICFs, aiming to ensure patient autonomy in orthodontic treatment decision-making and management.

4.9 Anna Wexler et.al (2021) (**AJOB Empirical Bioethics**) in their study **" Ethical Issues in Intraoperative Neuroscience Research: Assessing Subjects Recall of Informed Consent and Motivations for Participation"** This study investigated the ethical issues surrounding informed consent and voluntariness among Parkinson's disease patients involved in an intraoperative neuroscience study during deep brain stimulation (DBS) surgery. Two semi-structured interviews were conducted: one preoperatively, an average of 7.8 days after informed consent and 5.2 days before surgery, and one postoperatively, about 5 weeks after surgery. Out of 22 participants (mean age 60.9), 20 completed both interviews. Participants cited altruism and the advancement of medical science as key motivations, but showed poor recall of study details. Only 22.7% remembered one of two risks, with recall rates of 36.4% for the study's purpose, 50.0% for the protocol, and 36.4% for the benefits. Despite understanding that the study would not provide direct therapeutic benefits, participants' retention of information was low. These results highlight the need for improved informed consent processes to ensure ethical participation in such studies.

4.10 E Fischer MPH et al (2021) (South African Medical Journal) in their study **"The readability of informed consent forms for research studies conducted in South Africa"** This study focused on assessing the readability of informed consent forms (ICFs) in South Africa, using readability formulas in Microsoft Word. Evaluate if

current South African ICFs align with readability standards, particularly aiming for a Flesch-Kincaid Reading Grade score equivalent to grade 8 or lower. A descriptive study of English ICFs from the past 5 years, covering drug studies related to HIV, tuberculosis, diabetes, or cardiovascular disease. Flesch Reading Ease, Flesch-Kincaid Reading Grade, and Simple Measure of Gobbledygook (SMOG) were calculated. 75 consent forms from 35 studies were included. Median Flesch Reading Ease was 55.8, with 25% having easy or standard readability. Median Flesch-Kincaid Grade was 10.2, and 30.6% were at least at grade 8 level or lower. The median SMOG index was 9.8, and 5.3% scored below grade 8. Two-thirds of the ICFs in the study didn't meet South African readability standards. This result was consistent across different readability formulas. The study suggests that readability can be enhanced through simple techniques and active monitoring of readability metrics.

4.11 Giuseppe Pastore et al (2020) (Journal of Surgery) in their study **"Readability of foot and ankle consent forms in Queensland"** The study analyzed the readability of patient take-home information and consent forms for foot and ankle procedures in Queensland Health. Results indicated that the mean reading grade level for the risk information (section C) was 8.7 ± 0.9, patient consent (section G) was 11.6 ± 1.2, and procedure-specific take-home information was 7.5 ± 0.2. In conclusion, the readability of sections C and G in the consent forms surpassed national and international recommendations. However, the patient take-home information demonstrated a more suitable reading grade level. The study suggests the importance of reconsidering and lowering the reading grade level of patient consent forms to align with the literacy skills of the Australian population.

4.12 Lydia O'Sullivan et al (2020) (BMJ open) in their study **"Readability and understandability of clinical research patient information leaflets and consent forms in Ireland and the UK: a retrospective quantitative analysis"** This study aimed to assess the difficulty level of clinical research Patient Information Leaflets/Informed Consent Forms (PILs/ICFs) and compare them with best practice guidelines. The analysis involved 176 PILs from academic institutions, pharmaceutical companies, and investigators in Ireland and the UK. Seven validated readability criteria, two health literacy-based criteria, and six best practice metrics were employed.

Results showed that none of the PILs had the recommended reading age (<12 years) by the American Medical Association. Only 7.1% were rated 'Plain English,' while 40.3% were 'Fairly Difficult,' 51.3% 'Difficult,' and 1.3% 'Very Difficult.' None achieved a Clear Communication Index (CCI) >90, and only two complied with all six best practice literacy metrics. In conclusion, the PILs/ICFs assessed were deemed inappropriately complex by both traditional readability criteria and health literacy-based tools, indicating a clear need for improved documentation aligning with literacy agency guidelines.

4.13 Kevin Cin C. Lee DDS (2020) (Journal of Oral and Maxillofacial Surgery) in their study **"Online Patient Education Materials for Orthognathic Surgery Fail to Meet Readability and Quality Standards"** In this study assessing the readability and quality of online patient education materials (PEMs) for orthognathic surgery, the researchers conducted two internet searches using the search terms "orthognathic surgery" and "jaw surgery." The content related to risks, benefits, procedures, and postoperative care was recorded from 50 websites after removing duplicates and applying exclusion criteria. The readability of the PEMs was measured using four validated scales: the Flesch-Kincaid grade level, Gunning Fog index, Coleman-Liau index, and Simple Measure of Gobbledygook index. The results indicated that, on average, the PEMs were written at a 13.4grade level (range, 7.8 to 17.3). According to the American Medical Association (AMA) and the National Institutes of Health (NIH) recommendations, PEMs are considered readable if written at or below an eighth-grade reading level, suggesting that the materials in this study surpassed the recommended readability level. The quality of the PEMs was assessed using the DISCERN instrument and the Journal of the American Medical Association benchmark criteria. The mean DISCERN score was 25.5 out of 80 (range, 18 to 63), and only two websites achieved DISCERN scores of acceptable quality (score of 50). The study found that private practice websites had less content related to the surgical procedure (P=.03) and lower DISCERN scores (P=.02) compared to non-private practice websites. the online PEMs for orthognathic surgery, while exceeding recommended readability levels, fell short in terms of quality and content coverage. The study emphasizes the need for

improvement in the presence of content related to treatment risks and postoperative care to enhance the overall quality of PEMs in this domain.

4.14 Tiarnan O. Doinn BMBS et al (2020) (Journal of Arthroplasty) in their study **"Readability of Patient Educational Materials in Hip and Knee Arthroplasty: Has a Decade Made a Difference?"** This study delves into the readability of online patient educational materials (PEMs) related to hip and knee arthroplasty, sourced from major healthcare websites. The internet is a key health education resource, but recommended reading levels for patient materials are often not met. The study focuses on hip and knee arthroplasty PEMs. 134 articles from five leading worldwide healthcare websites were assessed using eight readability formulae. These include Flesch-Kincaid Reading Grade Level, Flesch Reading Ease Score, Raygor Estimate, SMOG, Coleman-Liau, Fry, FORCAST, and Gunning Fog. The mean cumulative Reading Grade Level was 12 (range 7-16.1). None of the articles met the 6th-grade reading level recommendation, and only 3% were at or below the 8th-grade level. The mean Reading Grade Level was significantly higher than both the 6th and 8th-grade recommendations. There was a significant difference in reading levels among the five websites. Patient educational materials on arthroplasty from leading healthcare organizations worldwide have readability scores above recommended levels.

4.15 Matthew Bange et al (2019) (Journal of the American College of Radiology) in their study **"Readability of Patient Education Materials from RadiologyInfo.org: Has There Been Progress Over the Past 5 Years?"** The 2017 study rigorously assessed 131 patient education articles on RadiologyInfo.org, sponsored by ACR and RSNA, employing six readability scales. Despite heightened awareness, the mean readability level exceeded the 11th grade, with none meeting the recommended 8th or 6th-grade standards. This persistent issue over 5 years underscores a gap between current practices and accessibility needs. The study's conclusion emphasizes the urgent necessity for continuous efforts to enhance the readability of radiological patient education materials, ensuring they align with recommended standards for broader comprehension and accessibility.

4.16 Varun Ayyaswami BS et al (2019) (American Journal of Health Education) in their study **"A Readability Analysis of Online Cardiovascular Disease-Related Health Education Materials"** The research focused on assessing the readability of frequently searched Internet health education materials related to cardiovascular diseases. The methodology involved selecting 20 commonly searched terms, querying them on Google, and analyzing up to 10 results for each term. This process yielded a comprehensive dataset of 196 patient education articles. The key findings unveiled that the average reading level of these articles was 10.9, with a standard deviation of 1.8. Notably, an overwhelming 99.5% of the articles exceeded the recommended 5th- to 6th-grade reading level advocated by the American Medical Association. In conclusion, the study emphasizes the significance of readability as a critical quality metric for online health education materials. The high complexity of the assessed articles suggests a potential barrier to effective patient comprehension. The researchers recommend further exploration into strategies to enhance the readability of online health content, anticipating improved patient education, engagement, and ultimately, better health outcomes.

4.17 Paul H. Yi, Meghan M. Yi, and Jie C. Nguyen (2018) (Journal of Pediatric Radiology) in their study **"Readability of Online Information Related to Pediatric Radiation Safety From Societal Websites"** This study aimed to evaluate the readability of online information on pediatric radiation safety from major healthcare sources. Assess the readability of publicly available online information on pediatric radiation safety from radiologic and pediatric societies. Information from the Society for Pediatric Radiology, RadiologyInfo, and HealthyChildren.org was evaluated for readability using six tests. ANOVA and intraclass correlation coefficients were used for analysis. 54 articles were analyzed, with three written below an eighth-grade reading level. The mean readability ranged from grades 12.1 to 14.8 on different scales. The numeric scale indicated a mean readability of 37.3 (categorized as difficult). 91% of articles were classified as very difficult, difficult, or fairly difficult, with none considered easy or very easy. No significant readability difference was found among

different web sources (p = 0.46–0.85). The information on pediatric radiation safety from Radiology and Pediatric Medical Society websites is generally too difficult for the average adult. This suggests a potential need for improving the accessibility and simplicity of such online health education materials.

4.18 Hector de la Mora-Molina M.D. (2018) (Arthritis & Rheumatology journal) in their study **"Trends of Informed Consent Forms for Industry-Sponsored Clinical Trials in Rheumatology over 17 years: Readability, and Assessment of Patients" Health Literacy and Perceptions"** The study aimed to analyze trends in informed consent forms (ICFs) for multinational clinical trials in rheumatology over 17 years. They assessed the readability of ICFs from 1999 to 2016, using the INFLESZ scale, and also evaluated patients' health literacy (HL) and perceptions of ICFs. The key findings include: The global mean readability of ICFs remained somewhat difficult to read or average from 1999 to 2016, with a stable score of 57 ± 3. The length of ICFs increased significantly from 1999 to 2005 (mean 13 ± 5 pages) to later years (mean 22 ± 8 pages). Health literacy assessments showed that 18% to 44% of patients had limited HL. In a perceptions questionnaire, 84% of patients reported understanding the ICF well, but 2% to 57% misunderstood basic concepts, such as the study drug name and placebo. The study concludes that despite attempts by regulatory agencies and various suggestions, there is still a disparity between the readability of ICFs, patients' health literacy, and their comprehension of ICFs, indicating an ongoing challenge in improving the informed consent process for clinical trials.

4.19 N Sivanadarajah et al (2017) (Journal of Clinical Research & Bioethics) in their study **"Informed consent and the readability of the written consent form"** The study evaluated the readability of orthopedic consent forms, specifically those endorsed by the British Orthopaedic Association (BOA) and the National Health Service (NHS) Consent Form 1. The Flesch Reading Ease Score (FRES) was employed for assessment. FRES for NHS Consent Form 1: 55.6, indicating a literacy level expected of an A-level student. Mean FRES for BOA summary consent forms (n=27): 63.6 (95% CI: 61.66.0). Mean FRES for BOA detailed consent forms (n=32): 68.9 (95% CI: 67.7–

70.0), correlating to the literacy expected of a 13–15-year-old.BOA detailed forms scored higher than summary forms ($p<0.001$). The demonstrates that BOA-endorsed standardized consent forms are more readable than NHS Consent Form 1, with detailed BOA forms being the easiest to comprehend. However, due to varying literacy levels, a significant portion of patients may face challenges in providing informed consent based on the written information provided.

4.20 David Richard Hansberry et al (2017) (Cancer Medicine journal) in their study **"Lung Cancer Screening Guidelines: How Readable Are Internet-Based Patient Education Resources?"** The study examines the readability of online patient education materials on lung cancer screening, prompted by the findings of the National Lung Screening Trial and the subsequent endorsement by various national societies. The researchers conducted searches on Google using terms such as "pulmonary nodule," "radiation," "low-dose CT," and "lung cancer screening." They downloaded and analyzed the first 20 online resources for each term, converting them into plain text for assessment using 10 established readability scales. The results indicate that the 80 analyzed articles have an average grade level of 12.6, with a standard deviation of 2.7. The grade levels ranged from 4.0 to 19.0. Notably, 62.5% of these articles require a level of education equivalent to high school, while 22.6% necessitate a college degree or higher (16th grade and above) for comprehension. A mere 2.5% of the analyzed materials align with the recommendations of the National Institutes of Health and American Medical Association, which advocate for patient education materials to be written at a 3rd- to 7th-grade reading level. The conclusion of the study raises concerns about the potential contribution of these online materials to a knowledge gap, hindering patients from enhancing their health literacy. The complexity of the content may impede the general patient population's ability to comprehend the information effectively.

4.21 Akhil Kher et al (2017) (Journal of Cardiovascular Nursing) in their study **"Readability Assessment of Online Patient Education Material on Congestive Heart Failure"** The research delved into the readability of online patient education materials related to congestive heart failure. The study, utilizing six readability

assessment tools, examined 100 websites generated from a Google search using the term "congestive heart failure." After applying selection and exclusion criteria, only 70 websites were included in the analysis. The findings revealed a stark reality—merely 5 out of the 70 websites adhered to the recommended sixth-grade readability level. The mean readability scores were as follows: Flesch-Kincaid Grade Level (9.79), Gunning-Fog Score (11.95), Coleman-Liau Index (15.17), Simple Measure of Gobbledygook (SMOG) index (11.39), and the Flesch Reading Ease (48.87). These metrics collectively underscore a notable gap between the complexity of the provided information and the recommended accessibility level for the general population. the majority of analyzed websites surpassed the sixth-grade readability level recommendations. This raises concerns about the potential impact on medical outcomes for patients. The study advocates for concerted efforts to tailor online patient education materials more effectively, ensuring they align with the literacy levels of the broader population. Addressing this issue could significantly enhance the overall accessibility and understanding of crucial health information online.

4.22 David R. Hansberry et al (2017) (**Emergency Radiology journal)** in their study **"Quantitative analysis of the level of readability of online emergency radiology-based patient education resources"** This study focuses on assessing the readability of online information related to emergency radiology, considering the significance of the internet as a major source of medical information. Using Google, 23 search terms related to emergency radiology were explored, and the top 10 results for each term were analyzed. A total of 230 articles were evaluated for their readability using ten reputable readability scales. The key findings reveal that, on average, the assessed articles were written at a 12.1 grade level. Only 2 out of the 230 articles (1%) aligned with the recommended third to seventh-grade reading level set by the National Institutes of Health (NIH) and the American Medical Association (AMA). Notably, 52% of the articles required at least a high school education (12th-grade level), and 7.3% exceeded undergraduate education (16th-grade level). the majority of emergency radiology-related patient education materials on websites do not adhere to the recommended reading levels by NIH and AMA. This discrepancy suggests that the average reader may not fully benefit from these information sources. Given the established link

between health literacy and health outcomes, addressing the readability of online content in radiology becomes crucial to enhance the overall understanding and utilization of health information by patients.

4.23 D.R. Hansberry, A.L. Donovan, et al (2017) (Spine Journal) in their study **"Enhancing the Radiologist-Patient Relationship through Improved Communication: A Quantitative Readability Analysis in Spine Radiology"** The purpose of the study indicates a concern about the health literacy skills of over 75 million Americans and the role of readability scores in assessing the understanding of patient education materials. The study focuses on evaluating the readability of websites dedicated to patient education for radiologic spine imaging and interventions. Eleven search terms related to radiologic spine imaging were used to search the public internet, and the top 10 links for each term were collected and analyzed. Readability scores were determined using 10 well-validated quantitative readability assessments from patient-centered education websites. The results of the study indicate that collectively, the 110 articles analyzed were written at an average grade level of 11.3, with a range of 7.1 to 16.9. None of the articles met the recommended 3rd-to-7th-grade reading levels suggested by the American Medical Association and National Institutes of Health. The study concludes by emphasizing the increasing use of the internet for health information and the importance of online patient education being written for easy comprehension by the average American. However, it expresses concern about the discordance between the readability scores of the articles and the recommended guidelines from medical associations, suggesting that many patients may not fully benefit from these resources.

4.24 Karan Kapoor et al (2017) (**Journal of the American College of Cardiology**) in their study **"Health Literacy: Readability of ACC/AHA Online Patient Education Material"** objective of this study was to assess whether online patient education materials from the American College of Cardiology (ACC) and the American Heart Association (AHA) exceeded the recommended 6th–7th-grade reading level by the National Institute of Health (NIH). The research involved analyzing 372 articles from the ACC website and 82 from the AHA using the Readability Studio Professional

Edition. The results indicated that the mean reading grade levels (RGLs) for the 454 articles were consistently higher than the NIH-recommended grade level of 6.5 and the 8th-grade national mean. Across various readability formulas—Flesch-Kincaid grade level, Simple Measure of Gobbledygook Index, Coleman-Liau Index, Gunning-Fog Index, New Dale-Chall reading level formula, FORCAST, Raygor Readability Estimate, and Fry Graph—the RGLs were found to be significantly elevated. The patient education material on both the ACC and AHA websites was written above the NIH-recommended 6.5 grade level and the 8th-grade national mean reading level. The study suggests a need for further research to explore whether lowering the reading grade level of this material could lead to improved outcomes among patients with cardiovascular disease.

4.25 Bente Hamnes et al (2016) (**Rheumatology International journal)** in their study **"Readability of patient information and consent documents in rheumatological studies"** This study delves into the alignment between the readability of patient information and consent documents (PICDs) and the educational levels of participants in rheumatological studies across the Netherlands, Denmark, and Norway. Gathering 24 PICDs, the researchers employed Gunning's Fog Index (FOG) and Simple Measure of Gobbledygook (SMOG) grading for independent assessments. The mean FOG and SMOG grades across all studies were 14.2 (9.0–19.0) and 14.2 (12–17) respectively. Notably, there were variations across countries, with Dutch studies scoring 12.7 and 13.3, Danish studies at 15.0 and 14.9, and Norwegian studies at 14.6 and 14.3 for FOG and SMOG grades, respectively. Critically, over 57% of the 2865 participants had an educational level lower than the highest readability score in their respective studies. The study's conclusion raises concerns about the validity of consent, suggesting that participants might not fully understand their agreement. The call for increased attention to PICD readability underscores the potential need for national guidelines to ensure clear, unambiguous, and easily understandable language in PICDs, ultimately enhancing the ethical conduct of medical research.

4.26 Tony Barnett, Ha Hoang, et al (2016) (Australian Dental Journal) in their study **"An analysis of the readability characteristics of oral health information literature**

available to the public in Tasmania, Australia" The study assessed print-based oral health information literature in Tasmania, Australia, collected from 11 dental clinics. 67 brochures were sampled. Flesch-Kincaid Grade Level (FKGL): The reading difficulty ranged from grade 3 to 13. Government Health Department Brochures (n=14) Reading levels ranged from grade 4 to 11 (average 5.6±1.8). Commercial Sources (n=22) Reading levels ranged from 3 to 13 (average 8.3±2.1). Professional Associations (n=22) Reading levels ranged from grade 7 to 11 (average 8.9±0.9). Other Sources (n=9): Reading levels ranged from 5 to 10 (average 7.6±1.5). SMOG Test Positively correlated with FKGL ($rs = 0.92$, $p<0.001$), consistently rating materials 2-3 grades higher. Government materials had lower average reading levels, fewer words, and less professional jargon compared to brochures from commercial, professional, and other sources. There's a range of oral health brochures in Tasmania, but readability varies. Many brochures may require a higher reading skill level than suitable for a significant portion of the population. The study emphasizes the need to assess and improve the readability of oral health education materials, especially for those with low literacy skills.

4.27 Satish Chandrasekhar Nair et al (2016) (**Middle East Journal of Clinical Research**) in their study **"Comparison of good clinical practice compliance and readability ease of the informed consent between observational and interventional clinical studies in the Emirates"** The text describes a study investigating the expansion of clinical trials, particularly observational studies, in emerging regions like the United Arab Emirates (UAE). The research compares informed consent forms (ICFs) between observational and interventional studies, focusing on content, Good Clinical Practice (GCP) compliance, and readability. The findings indicate that GCP compliance for observational studies averaged 79.5% ± 6.8%, significantly lower ($P < 0.001$) than the 92.2% ± 5.0% observed for interventional studies. Readability analysis using Flesch-Kincaid scales revealed a higher readability grade level (12.4 ± 0.4, $P < 0.001$) and lower readability Flesch-Kincaid reading ease score (35.7 ± 3.6) for observational studies compared to interventional studies (grade level: 10.3 ± 1.6, reading ease score: 47.8 ± 7.4). The conclusion emphasizes the imperative for mandatory investigator training to improve readability and ensure GCP compliance in

ICFs, specifically tailored for the local population in the UAE. The study underscores concern about participant rights and ethical standards in clinical trials conducted in developing economies.

4.28 Kevin Won, Jessica R. Levi et al (2016) (International Journal of Pediatric Otorhinolaryngology) in their study **"Readability of Pediatric Otolaryngology information by Children's Hospitals and Academic Institutions"** This analysis aims to evaluate the readability of pediatric otolaryngology–related patient education materials sourced from prominent online platforms. We collected articles from the online patient health libraries of the top 10 US News & World Report-ranked children's hospitals, the top 5 Doximity-ranked pediatric otolaryngology fellowships, and the American Academy of Otolaryngology-Head and Neck Surgery. After extracting and formatting the content, readability metrics including the Flesch-Kincaid Grade Level, Flesch Reading Ease Score, Gunning-Fog Index, Coleman-Liau Index, Automated Readability Index, and Simple Measure of Gobbledygook were calculated. A total of 502 articles were analyzed. Excellent intraobserver and interobserver reliability were observed (intraclass correlation coefficient of 0.99 and 0.96, respectively). Only 142 articles (28.3%) were written at or below the reading ability of the average American adult, while the remaining 360 articles (71.7%) were written above the reading level of the average adult. The findings indicate that the current online health information related to pediatric otolaryngology may be too challenging for the average reader to comprehend. A significant majority (71.7%) of the analyzed articles were written above the reading level of the average adult. Revisions may be necessary to ensure that these materials effectively benefit a larger readership. The study suggests that revisions to current online health information on pediatric otolaryngology are needed to enhance readability and cater to a broader audience.

4.29 Gaiyan Wen et al (2016) (Chinese Journal of Clinical Oncology) in their study **"Readability and Content Assessment of Informed Consent Forms for Phase II-IV Clinical Trials in China"** The comprehensive examination of 155 informed consent forms (ICFs) from phase II-IV drug clinical trials in China, conducted by the

Third Xiangya Hospital Ethics Committee between November 2009 and January 2015, revealed insightful findings. The ICFs exhibited a median length of 5286 words, approximately 7 pages. Readability, assessed with a Chinese-adapted formula, yielded a median score of 4.31, predominantly falling at the 2nd reading level (63.9%) and the 3rd level (36.1%). The study identified neglect in five out of 27 crucial content integrity elements. An assessment of describing alternatives to participation resulted in an average score of 1.06; alarmingly, 27.7% of ICFs lacked any information on alternatives. In comparison with international standards, Chinese ICFs were characterized by shorter length, lower readability, and fewer included elements, displaying statistical significance ($P < 0.05$). The study concludes by emphasizing the challenges Chinese ICFs pose in terms of readability and content integrity. Deficiencies were identified in crucial aspects such as informed consent explanation, follow-up procedures, inclusion/exclusion criteria, double-blinding, and unpredictable risks. International ICFs surpassed their Chinese counterparts in both readability and content integrity. The research advocates for collaborative efforts to enhance the quality of consent documents in China, emphasizing the imperative need for clearer and more comprehensible information to ensure the ethical conduct of clinical trials.

4.30 Luka Vučemilo, Ana Borovečki, et al (2015) (Croatian Medical Journal) in their study **"Readability and Content Assessment of Informed Consent Forms for Medical Procedures in Croatia"** The study conducted a comprehensive assessment of 52 informed consent forms utilized for diagnostic and therapeutic procedures across six Croatian hospitals. The investigation disclosed that the average readability level, as determined by the Simple Measure of Gobbledygook (SMOG) formula adapted for the Croatian language, was notably high, with an average SMOG grade of 13.25. This suggests a potential challenge in comprehension for the general population. While the forms generally provided detailed information on risks (96% coverage), certain crucial aspects exhibited notable deficiencies. Descriptions of benefits were included in 81% of cases, leaving room for improvement in conveying potential positive outcomes. Moreover, the depiction of procedures was found in 78% of instances, indicating that while this aspect is covered, there is still a significant portion of forms lacking in this regard. A critical observation was the limited coverage of alternatives, with only 52%

of forms addressing this important aspect of informed decision-making. Further deficiencies were noted in the discussion of risks and benefits associated with alternatives (17% coverage) and the risks and benefits of not undergoing treatment or procedures (13% coverage). The implications of these findings underscore the necessity for a comprehensive review and enhancement of both the readability and content of informed consent forms in Croatian hospitals. The high reading difficulty identified may hinder patients' ability to fully comprehend the information presented, compromising their capacity to make informed decisions. This study's insights are particularly pertinent in the context of ongoing hospital accreditation processes in Croatia. The identified shortcomings provide a basis for recommending improvements in informed consent practices as part of a broader initiative to enhance overall healthcare services. Recommendations for improvement include employing plain language principles, simplifying language, and potentially supplementing materials to enhance patient understanding and facilitate informed decision-making. Overall, the study highlights the urgency of addressing these issues to ensure that patients receive comprehensive and understandable information during the informed consent process.

4.31 Shlomo A. Koyfman MD et al (2015) (Journal of Medical Ethics) in their study **"Informed Consent Conversations and Documents: A Quantitative Comparison"** The study investigated informed consent documents (ICDs) and informed consent conversations (ICCs) in pediatric phase I oncology trials, audio recording ICCs at six institutions. Comparisons revealed that ICCs contained fewer words (4677 vs. 6364 words), had a lower Flesch-Kincaid Grade Level (FKGL) (6 vs. 9.7), and a higher Flesch Reading Ease score (FRES) (77.8 vs. 56.7) than their corresponding ICDs. Despite their higher readability, ICCs were more likely to omit critical consent elements, with voluntariness omitted in 55% and dose-limiting toxicities in 26% of cases. Notably, years of investigator experience showed no correlation with reliable coverage of critical elements or decreased linguistic complexity. The study suggests the importance of communication training for clinician-investigators to enhance the informed consent process, given the disparities observed in length, readability, and coverage of critical elements between ICCs and ICDs.

4.32 Shlomo A. Koyfman et al (2013) (Cancer journal) in their study **"Consent Form Heterogeneity in Cancer Trials: the Cooperative Group and Institutional Review Board Gap"** The study aimed to compare the readability and length of consent forms (CFs) in cancer clinical trials provided by Cooperative Groups (CG) with those subjected to re-review and revision by local Institutional Review Boards (IRB). A total of 197 CFs from 56 CG trials, open in at least two participating institutions, were analyzed. The findings revealed that IRB-approved consent forms (IRB-CFs) were statistically significantly longer than CG-provided consent forms (CGP-CFs), with a mean of 17 pages compared to 13 pages ($P < .001$). Additionally, IRB-CFs exhibited higher Flesch–Kincaid Grade Levels (FKGLs) and lower Flesch Reading Ease Scores (FRESs) than CGP-CFs, indicating a trend towards increased complexity and decreased readability in the former. Further analysis demonstrated significant variability in readability across institutions for all sections of the IRB-CF ($P < .0001$). The study suggests that as consent forms progress from National Cancer Institute (NCI)–sponsored CGs to local IRBs, they become longer and less readable. The observed heterogeneity in readability and length across institutions underscores the importance of standardizing the consent form development and review process. The authors recommend more consistent adherence to CGP-CFs based on the newly revised NCI CF template, with minimal modifications by local IRBs, to simplify and standardize CFs used in cancer clinical trials.

4.33 Adam Nishimura et al (2013) (**Journal of Clinical Ethics**) in their study **"Improving Understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials"** This study systematically analyzed 39 randomized controlled trials (RCTs) comprising 54 interventions aimed at improving informed consent in biomedical research. Conducted up to September 2010, the research covered databases like Ovid MEDLINE and Scopus. Intervention categories included multimedia, enhanced consent forms, extended discussions, test/feedback quizzes, and miscellaneous methods. Primary outcomes focused on participant understanding, with secondary outcomes including information retention, satisfaction, and accrual rates. Meta-analysis of 22 interventions revealed that enhanced consent forms and extended discussions significantly improved

participant understanding, while multimedia approaches showed a non-significant increase. A qualitative review found enhanced consent forms and extended discussions to be the most effective, with notable percentages of interventions within these categories showing significant improvements. Importantly, these interventions did not negatively impact participant satisfaction or study accrual. The study recognized variations between studies, such as control processes and assessment formats. In conclusion, the research emphasized the importance of identifying best practices for informed consent interventions to enhance participant understanding in biomedical research. The findings highlight the need for tailored approaches and consideration of contextual factors in future comparisons, offering valuable insights for researchers and policymakers aiming to improve ethical research practices.

4.34 Danielle M. McCarthy et al (2012) (Journal of Emergency Medicine) in their study **"Language Use in the Informed Consent Discussion for Emergency Procedures"** This study aimed to investigate the structural elements of residents' spoken words during informed consent discussions, with a focus on comparing physician and patient speech patterns. The research involved 26 resident physicians engaging in simulated informed consent discussions with standardized patients. The audio recordings of these discussions were transcribed and analyzed to evaluate grammar statistics, such as language complexity measured in reading grade level. Additionally, transcripts and time values were utilized to assess the structural characteristics of the dialogue, particularly interactivity. The key findings indicate that the discussions were marked by physician verbal dominance. While interactive, there were significant differences in language complexity metrics between physician and patient speech patterns. Specifically, physicians tended to speak significantly more and use more complex language compared to the patients. This information sheds light on an important aspect of healthcare communication, highlighting the potential disparities in language complexity between healthcare providers and patients during informed consent discussions. Further research and interventions may be warranted to enhance the clarity and accessibility of spoken health communication, ensuring that patients can fully comprehend and participate in decision-making processes.

4.35 Leonardo Tamariz et al (2012) (Journal of Health Communication) in their study **"Improving the Informed Consent Process for Research Subjects with Low Literacy: A Systematic Review"** The text discusses a study aiming to assess interventions that improve comprehension of the informed consent (IC) process in individuals with low health literacy. The researchers conducted a thorough search, identifying six eligible studies with 1620 participants, predominantly older and from ethnic minority groups with low literacy. Only one study had a randomized design. Different interventions were tested, with the teach-back method showing the highest comprehension in two studies, while changing the readability level of the IC resulted in the lowest comprehension in two studies. The overall evidence supporting interventions in low literacy populations is extremely limited. One-on-one interaction with study participants appeared to be the most effective strategy, but this finding is based on a single study. The study underscores the challenges and the need for further research to establish more robust guidelines for improving IC comprehension in individuals with low health literacy.

4.36 ER Ezeome et al (2011) (Nigerian Journal of Clinical Practice) in their study **"Contents and readability of currently used surgical/ procedure informed consent forms in Nigerian tertiary health institutions"** The study examines surgical and procedure informed consent forms from 33 Federal tertiary health institutions in Nigeria and identifies notable shortcomings: No forms document patient permission for blood transfusion, tissue disposal, or awareness of treatment risks. Only 11.4% of forms provide detailed risk disclosures. Less than 10% of forms include provisions for an interpreter, anesthetist signatures, alternative procedures, and addressing patient questions. Flesch readability scores range from 34.1 (Difficult) to 67.5 (Standard), with a mean score of 55.2 (Fairly difficult level). Implying potential comprehension barriers, particularly for less educated patients. The readability scores of the Nigerian forms are not better than those used in developed parts of the world. Urges a comprehensive revision of consent forms to enhance content and readability. Emphasizes the need for usability trials on revised forms before deployment. In summary, the study quantifies the deficiencies in informed consent forms, indicating a need for urgent improvement

in content and readability in Nigerian tertiary health institutions. The numbers provide a clear picture of the extent of these shortcomings.

4.37 Marli Terblanche, Lesley Burgess, et al (2010) (Journal of Medical Ethics) in their study **"Examining the readability of patient-informed consent forms"** The study examines the readability of informed consent forms (ICFs) at TREAD Research, a clinical trial unit in Tygerberg Hospital, between 2000 and 2009. Using various readability measures, including Flesch–Kincaid Reading Ease and Grade Level, and Gunning-Fog index, the analysis finds that the ICFs are generally too complex for average participants and their families. The results indicate a lack of readability at an eighth-grade level, with no significant differences observed between therapeutic areas or over time. The main conclusion is that the ICFs assessed are challenging for study participants to understand. Keywords include informed consent forms, readability, and literacy.

4.38 Michael Jefford, Rosemary Moore et al (2008) (Journal of Clinical Research & Bioethics) in their study **"Improvement of informed consent and the quality of consent documents"** The significance of informed consent in ethical research, emphasizes the need for participants to understand the various aspects of clinical trials. Common issues with written consent forms, such as length and language complexity, are discussed. The analysis suggests strategies, including the use of plain language, to improve the clarity of consent forms in clinical research. Recommendations are provided to enhance discussions between investigators and patients, aiming to improve participant comprehension and satisfaction in the informed-consent process.

4.39 James Flory, BA et al (2004) (BMC Medical Ethics journal) in their study **"Interventions to Improve Research Participants' Understanding in Informed Consent for Research"** The study conducted a comprehensive review of interventions aimed at enhancing research participants' understanding of information disclosed in the informed consent process. Drawing from a search of MEDLINE and additional sources, the review encompassed 42 trials meeting inclusion criteria. Results indicated that multimedia interventions had limited success, with only three out of twelve trials

showing a significant improvement in understanding. Enhanced consent forms, while showing improvement in six out of fifteen trials, were marred by concerns about their practical relevance in five instances due to limited quality. Extended discussion, involving one-on-one interactions, emerged as the most effective method, with three out of five trials showing significant improvement and two displaying trends toward enhancement. Test/feedback interventions, although all demonstrating significant improvement, were criticized for potentially mistaking rote memorization for genuine understanding. A miscellaneous category of interventions displayed varying impacts on understanding. Demographic factors, particularly lower education levels, were associated with diminished understanding. Encouragingly, interventions did not compromise participants' satisfaction or willingness to enroll in clinical trials. The study concluded that while efforts using multimedia and enhanced consent forms had limited success, one-on-one interactions with study team members or neutral educators appeared to be the most effective approach, emphasizing the need for further research in this domain.

4.40 Michael K. Paasche-Orlow et al (2003) (**Journal of Clinical Trials**) in their study **"Readability Standards for Informed-Consent Forms as Compared with Actual Readability"** The study evaluates the readability of informed-consent forms provided by Institutional Review Boards (IRBs) in U.S. medical schools. Findings reveal that IRBs often fail to meet their readability standards, with an average readability score of 10.6 on the Flesch–Kincaid scale. While factors like research funding and local literacy rates show no influence, federal oversight by the Office for Human Research Protections is associated with improved readability. The study underscores the need for IRBs to enhance the readability of consent forms for better comprehension by research subjects.

4.41 L. Molina et al (2001) (Journal of Women's Health) in their study **"Readability of education materials and informed consent forms for women seeking surgical sterilization"** Health education material and consent forms written in both English and Spanish distributed to low-income Hispanic women seeking surgical sterilization bilateral tubal ligation. Contraception Sterilization Consent form 23 28 41 92 15 16 14

45 25 36 55 106 9.6q 3 s 12.6 handout entitled 'Your Sterilization Operation' written under the auspices of the municipal hospital, offered a comprehensive description of the tubal ligation procedure. Finally, the consent form which must be read, understood, and signed by the sterilization candidate before she is permitted to undergo surgery was estimated to require 13.8 years, the equivalent of 2 years of college education to fully comprehend. In a pilot study that examined their understanding of educational materials and consent forms used in the education session. Among the readers of the health education material, 91% correctly listed alternative contraceptive methods 29% could not list potential side effects associated with the surgery. Though the analysis is very preliminary, it points towards the need for readable healthcare materials for patient populations of all literacy levels in general, and for populations with literacy or language proficiency challenges in particular.

CHAPTER – 5

METHODOLOGY

5.1 SOURCE OF DATA

Informed Consent Forms:

Selection: The primary source of data for this study comprises radiological informed consent forms obtained from a diverse range of healthcare institutions within the Delhi NCR region. These institutions include hospitals and diagnostic centers known for their radiological services.

Criteria: Consent forms were selected to ensure representation across various types of radiological procedures and a range of patient demographics. The selection process aimed to capture a broad spectrum of readability levels and institutional practices.

Readability Software:

Readability analysis was conducted using established readability software tools, which calculate the Flesch-Kincaid Grade Level (FKGL) and Flesch Reading Ease Score (FRES) for each consent form. These tools provide objective measures of text complexity and readability.

Human Evaluators:

Participants: A sample of individuals, including patients and non-medical professionals, was selected to evaluate the readability of the consent forms.

Evaluation: These individuals provided subjective readability scores based on their understanding and interpretation of the consent forms, offering additional insights into the accessibility of the documents.

Comparative Data:

Source: The National Family Health Survey (NFHS-5) data for Delhi NCR was used to contextualize the readability scores. This data provided information on the educational attainment

levels of the local population, facilitating a comparison between consent form readability and expected reading abilities.

5.2 METHOD OF COLLECTION OF DATA

A random selection of a diverse sample of informed consent forms from various healthcare institutions in Delhi NCR was conducted.

Additionally, a separate group of randomly selected individuals was asked to review the same consent forms. These individuals provided their own readability scores based on their understanding and application of the readability formulas. This dual approach allowed for a comparison between software-generated scores and those provided by human evaluators, offering a comprehensive assessment of the consent forms' readability and comprehensibility.

5.3 STUDY DESIGN

Descriptive Cross-Sectional Study: This study will be descriptive in nature, aiming to assess and compare the readability of radiological informed consent forms across various healthcare institutions in the Delhi NCR region at a single point in time.

5.4 STUDY PERIOD

The study was conducted over one year, starting in September 2023 and concluding in September 2024.

5.5 STUDY POPULATION

Public Hospitals: Large government hospitals that cater to a broad demographic, including institutions and other major government hospitals in the Delhi NCR region.

Private Hospitals: Prominent private hospitals are known for their radiological services.

Diagnostic Centers: Independent diagnostic and imaging centers that specialize in radiological procedures, ensuring a mix of both high-volume and smaller centers.

Clinics: Smaller clinics offering radiological services, which may have different informed consent practices compared to larger institutions.

5.6 SAMPLE SIZE

1. Informed Consent Forms:

The study will include a total of 30 radiological informed consent forms. This sample size is selected to ensure a comprehensive representation of readability across different types of radiological procedures and healthcare institutions within the Delhi NCR region.

2. Human Evaluators:

The study will involve 30 human evaluators. This sample size is chosen to provide a diverse range of perspectives on the readability of the consent forms.

5.7 SAMPLING PROCEDURE

1. Sample Selection for Informed Consent Forms:

- **Sampling Method:** A stratified random sampling approach will be used to ensure representation from various types of healthcare institutions, such as public and private hospitals, as well as diagnostic centers.
- **Form Selection:** Within each selected institution, consent forms for a range of radiological procedures (e.g., X-rays, CT scans, MRIs) will be randomly chosen to cover different types of imaging and variations in form design.

2. Sample Selection for Human Evaluators:

- **Recruitment**: Human evaluators will be recruited through public announcements, healthcare centers, and community outreach. Potential participants will be selected to represent a diverse range of age groups, education levels, and socioeconomic backgrounds.
- **Inclusion Criteria:** Participants must be able to read and understand English or the language in which the consent forms are written. They should also be over 18 years old.
- **Randomization:** Participants will be randomly assigned to evaluate different sets of consent forms to avoid bias and ensure that each form is assessed by individuals with varied backgrounds.

5.8 INCLUSION CRITERIA

Informed consent forms were collected from various healthcare Institutions in Delhi NCR and only radiological Informed Consent Forms were collected.

5.9 EXCLUSION CRITERIA

- Excluding Non-Radiological Informed Consent forms,
- Non-English Language,
- Emergency Procedures,
- Non-Consenting Institutions.

5.10 DATA COLLECTION PROCEDURE

1. Collection of Informed Consent Forms:

- **Institutional Coordination:**
    - **Form Retrieval:** Coordinate with the administrative or medical records departments of each institution to gather a representative sample of radiological informed consent forms.

- **Anonymization:** Anonymize the consent forms to ensure that no patient-specific information is included in the analysis. Assign unique identifiers to each form for tracking purposes.

2. **Collection of Readability Scores:**

- **Readability Analysis:**
  - **Software Analysis:** Use readability analysis software to compute scores based on established formulas such as Flesch-Kincaid Grade Level (FKGL) and Flesch Reading Ease Score (FRES). Input the digitized consent forms into the software and record the readability scores.
  - **Human Evaluators:**
    - **Training:** Conduct a training session for human evaluators to familiarize them with the readability criteria and scoring methods.
    - **Evaluation:** Provide evaluators with a subset of the consent forms to read and score based on their understanding of readability. Ensure that evaluators are instructed to assess factors such as clarity, complexity, and overall comprehensibility.

5.11 DATA ANALYSIS

• The data were inputted into an Excel spreadsheet.

• The data analysis for this study will involve a systematic approach to evaluating the readability of radiological informed consent forms across healthcare institutions in Delhi NCR. Quantitative analysis will focus on applying established readability formulas, including the Flesch-Kincaid Grade Level, and Flesch Reading Ease, to calculate readability scores for each form. Statistical techniques such as descriptive statistics and inferential test ANOVA will be used to compare readability scores between different types of institutions and assess factors influencing readability.

Readability Assessment Tools were used are:

Utilizing the Flesch Reading Ease formula as a standardized tool to quantitatively measure the readability of radiological informed consent forms.

Flesch Reading Ease Formula:

The Flesch Reading Ease score is calculated using the following formula:

$$\text{FRES} = 206.835 - 1.015\left(\frac{total\ sentences}{total\ words}\right) - 84.6\left(\frac{total\ syllables}{total\ words}\right)$$

Where:

- **Total Words** is the number of words in the text.
- **Total Sentences** is the number of sentences in the text.
- **Total Syllables** is the number of syllables in the text.

This formula yields a score on a scale from 0 to 100, with higher scores indicating easier readability. Interpretation of scores is as follows:

FRES Score	**Readability Level**
0-30	Very Difficult (College Graduate)
31-50	Difficult (College Level)
51-60	Fairly Difficult (10th-12th Grade)
61-70	Standard (8th-9th Grade)
71-80	Easy (7th Grade)
81-90	Very Easy (6th Grade)
91-100	Extremely Easy (5th Grade or Below)

Flesch-Kincaid Grade Level:

Is a readability test that indicates the readability level of a text by assigning it a grade level. It estimates the level of education a person needs to understand the text. The formula for calculating the Flesch-Kincaid Grade Level is:

$$FKGL=0.39\left(\frac{total\ sentences}{total\ words}\right)+11.8\left(\frac{total\ words}{total\ syllables}\right)-15.59$$

Where:

- **Total words** is the number of words in the text.
- **Total sentences** are the number of sentences in the text.
- **Total syllables** is the number of syllables in the text.

FKGL Score	**Grade Level**
0-30	College Graduate
31-40	College Senior
41-50	College Junior
51-60	10th-12th Grade
61-70	8th-9th Grade
71-80	7th Grade
81-90	6th Grade
91-100	5th Grade or Below

The result is a number typically corresponding to a grade level in the U.S. education system. For example, a Flesch-Kincaid Grade Level of 8.0 means that an eighth-grader should be able to understand the text.

Analysis of Evaluator Scores:

- **Score Collection:** Collect scores from a diverse sample of individuals who evaluated 30 randomly selected consent forms.
- **Criteria Alignment:** Ensure that the evaluators used the same criteria for scoring as outlined in the readability formulas (FKGL and FRES).
- **Correlation Analysis:** Perform correlational analysis to compare the readability scores given by the evaluators with those generated by the software. This will help in understanding the consistency and reliability of human evaluations against automated readability assessments.

4.12 ETHICAL APPROVAL

Ethical approval was obtained from the Ethical Committee of Santosh Deemed to be University, Ghaziabad.

CHAPTER – 6

RESULTS

This section presents the comprehensive findings of the study, which was conducted to evaluate the readability of a diverse selection of texts using the Flesch-Kincaid Grade Level (FKGL) and Flesch Reading Ease Score (FRES) formulas. The primary objective of the analysis was to determine the readability levels across various educational stages and to assess the effectiveness of these formulas in differentiating text complexity. By doing so, the study aims to provide insights into how these readability measures can be applied to ensure that texts are appropriately matched to their intended audience's reading capabilities.

The following sections present the detailed findings of the analyses, beginning with the FKGL results, followed by the FRES results. Each set of results is accompanied by a discussion of the implications for the intended audience's reading capabilities.

Flesch-Kincaid Grade Level (FKGL) Results

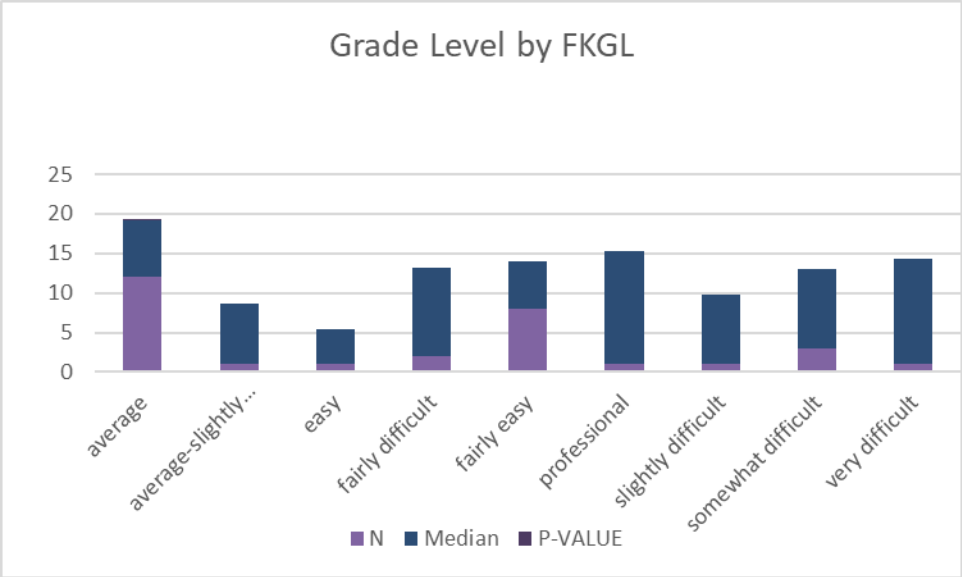
The FKGL analysis categorized texts into various educational levels, ranging from elementary to college grade levels.

Table no 1 Shows the FKGL scores and their corresponding grade levels:

Grade Level	Number of Texts (N)	Median FKGL Score	P-Value
7th grade	12	7.11	0.001
College	2	13.80	-
Eighth grade	1	7.58	-
Eleventh grade	2	11.20	-
Fifth grade	1	5.83	-
Fourth grade	1	4.36	-
Ninth grade	1	8.78	-
Sixth grade	7	6.07	-
Tenth grade	3	10.04	-

Table no.1 The analysis of FKGL scores reveals significant differentiation in text complexity across the educational stages, with a notable median FKGL score of 7.11 for texts aimed at seventh-grade readers. This is statistically significant, as indicated by the p-value of 0.001, suggesting that the FKGL formula reliably categorizes text readability for this grade level.

Graph no. 1 Shows the FKGL scores and their corresponding grade levels.



Graph no. 1 This distribution indicates that the majority of the informed consent forms analyzed are written at a 7th-grade reading level, with a significant number also at the 6th-grade level. This suggests that these forms are relatively easy to read for individuals with a middle school education. However, some forms are more complex, requiring a higher educational level to understand, including those written at the 10th-grade, 11th-grade, and college levels.

Flesch Reading Ease Score (FRES) Results

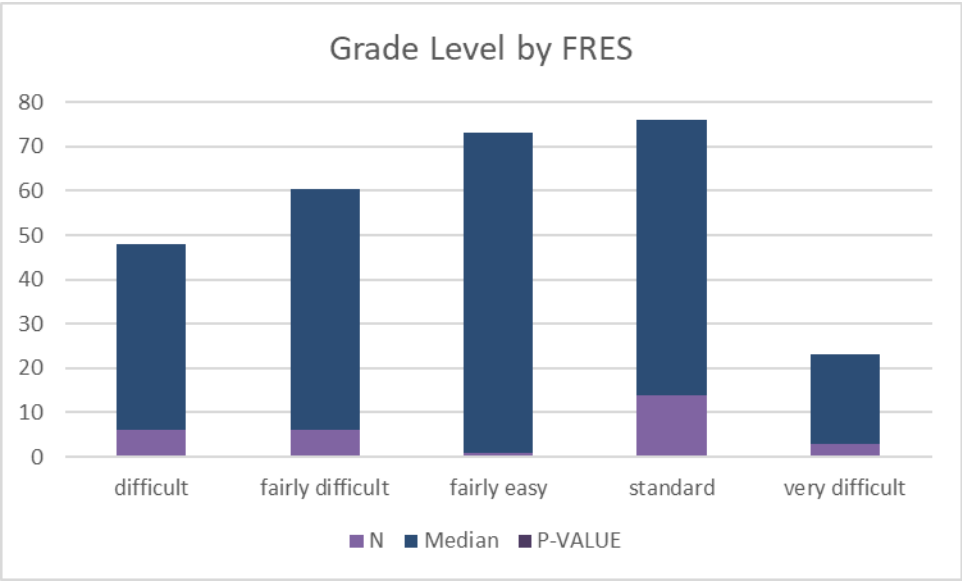
The FRES analysis also categorized texts according to their readability scores, providing a broader understanding of text complexity.

Table no. 2 Shows the FRES scores and their corresponding grade levels:

Grade Level	Number of Texts (N)	Median FRES Score	P-Value
10th & 12th grade	6	54.50	0.000
7th grade	1	72.00	-
8th & 9th grade	13	62.00	-
College	7	42.00	-
Professional	3	20.00	-

Table no. 2 The FRES results indicate significant variations in readability across the texts, with a median FRES score of 54.50 for texts suitable for tenth and twelfth graders, which is statistically significant with a p-value of 0.000. This demonstrates that the FRES formula effectively captures the readability differences among texts aimed at different educational stages.

Graph no.2 Shows the FRES scores and their corresponding grade levels



Graph no.2 This distribution indicates that the majority of the informed consent forms analyzed are written at an 8th and 9th-grade reading level, with a significant number also at the college level. This suggests that these forms are relatively accessible to individuals with a high school education. However, some forms are more complex, requiring a higher educational level to understand, including those written at the 10th and 12th-grade levels and professional levels.

The study assessed the readability of radiological informed consent forms from various hospitals in Delhi NCR using two metrics: the Free Reading Ease Score (FRES) and the Flesch-Kincaid Grade Level (FKGL). These metrics provide insights into the comprehensibility of the forms across different educational levels.

Table no 3 Shows the Readability Scores for Informed Consent Forms

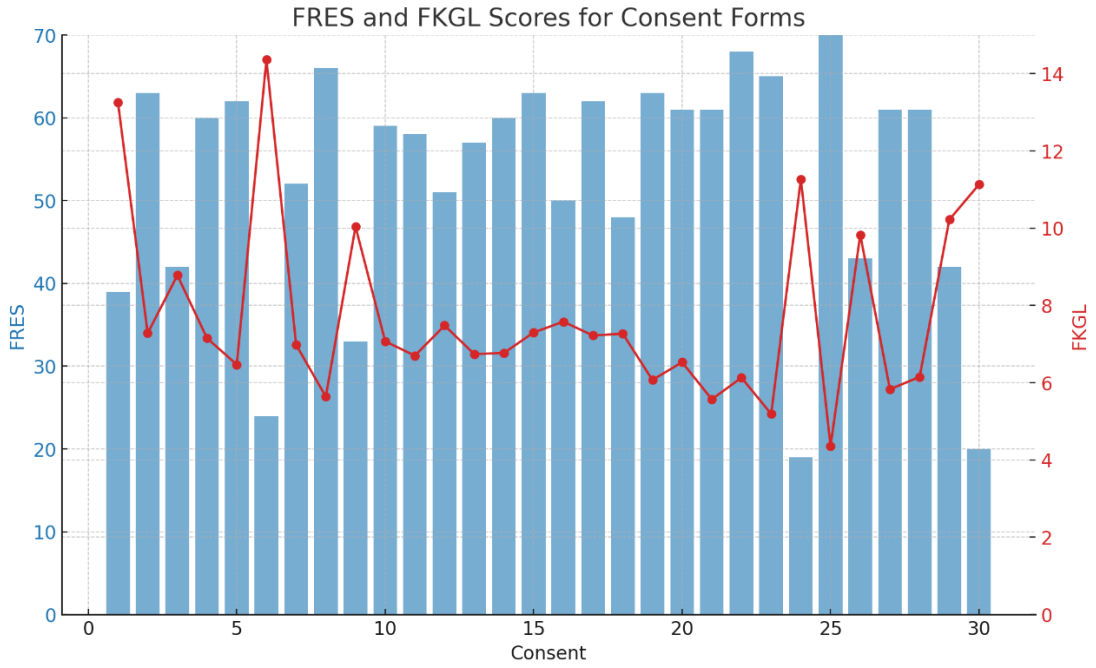
CONSENT FORM	FRES	FKGL
CONSENT 1	39	13.25
CONSENT 2	63	7.28
CONSENT 3	42	8.78
CONSENT 4	60	7.15
CONSENT 5	62	6.47
CONSENT 6	24	14.36
CONSENT 7	52	6.98
CONSENT 8	66	5.64
CONSENT 9	33	10.04
CONSENT 10	59	7.07
CONSENT 11	58	6.70
CONSENT 12	51	7.48
CONSENT 13	57	6.74
CONSENT 14	60	6.77
CONSENT 15	63	7.30
CONSENT 16	50	7.58

CONSENT 17	62	7.22
CONSENT 18	48	7.27
CONSENT 19	63	6.07
CONSENT 20	61	6.53
CONSENT 21	61	5.57
CONSENT 22	68	6.13
CONSENT 23	65	5.19
CONSENT 24	19	11.27
CONSENT 25	72	4.36
CONSENT 26	43	9.83
CONSENT 27	61	5.83
CONSENT 28	61	6.15
CONSENT 29	42	10.22
CONSENT 30	20	11.13

Table no 3 The FRES scores range from 19 to 72, indicating substantial variability in readability. Higher FRES scores suggest easier readability, whereas lower scores indicate more challenging text. For instance, Consent 25 has the highest FRES score of 72, indicating it is relatively easy to read, whereas Consent 24 has a low FRES score of 19, suggesting it is very difficult to comprehend.

Similarly, the FKGL scores range from 4.36 to 14.36, with lower scores indicating simpler language suitable for lower educational levels. Consent 25 has the lowest FKGL score of 4.36, meaning it is written at approximately a 4th-grade reading level, whereas Consent 6 has the highest FKGL score of 14.36, indicating it is written at a highly complex level suitable for advanced education.

Graph no.3 Shows the charts for Flesch Reading Ease Score (FRES) and Flesch-Kincaid Grade Level (FKGL) for the consent forms.



Graph no.3 Shows the charts for the Flesch Reading Ease Score (FRES) and Flesch-Kincaid Grade Level (FKGL) for the consent forms:

Flesch Reading Ease Score (FRES) Chart:

•This chart shows the readability score for each consent form.

•Higher scores indicate easier readability.

Flesch-Kincaid Grade Level (FKGL) Chart:

•This chart shows the grade level required to understand each consent form.

•Lower scores indicate simpler text that can be understood by younger students.

Table no. 4 Shows the mean, median, mode, and standard deviation for software-generated scores for both FKGL AND FRES.

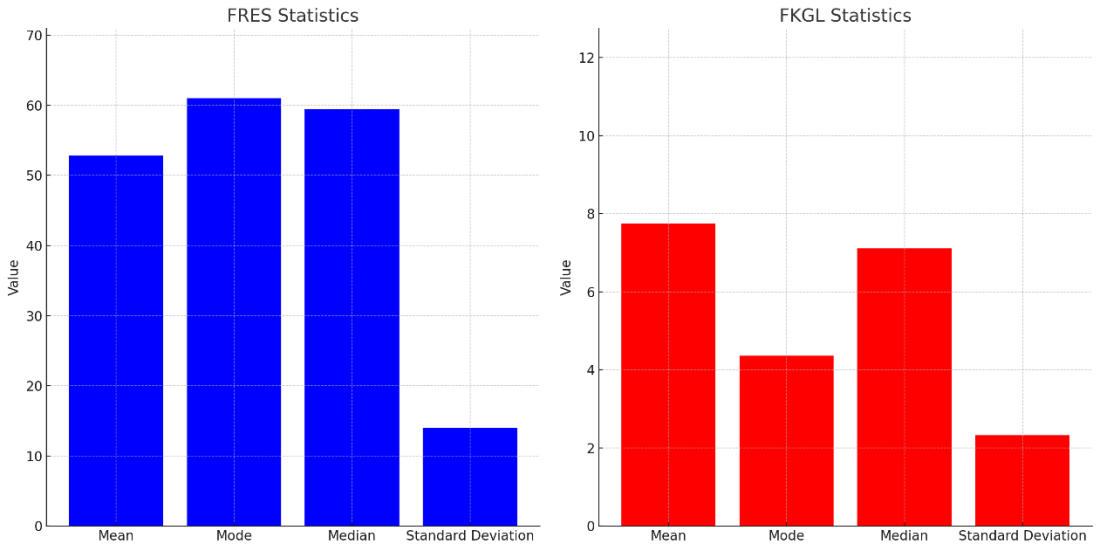
Statistic	FRES	FKGL
Mean	52.83	7.75
Mode	61	4.36
Median	59.5	7.11
Standard Deviation	13.97	2.32

Table no. 4 The table summarizes the readability of radiological informed consent forms in Delhi NCR using Flesch Reading Ease Score (FRES) and Flesch-Kincaid Grade Level (FKGL). The average FRES is 52.83, indicating moderate difficulty, with scores ranging from easy to difficult. The mode is 61, and the median is 59.5, with a standard deviation of 13.97, showing moderate variability.

The average FKGL is 7.75, suggesting the text is suitable for an 8th-grade reading level. The mode is 4.36, and the median is 7.11, with a standard deviation of 2.32, indicating some variability but mostly clustered around the mean.

Overall, while the average readability is around the 7th to 8th-grade level, the scores vary, highlighting the need for standardizing consent forms to ensure they are accessible to all patients.

Graph no. 4 Shows the mean, median, mode, and standard deviation for software-generated scores for both FKGL AND FRES.



Comparative Analysis with NFHS-5 Data

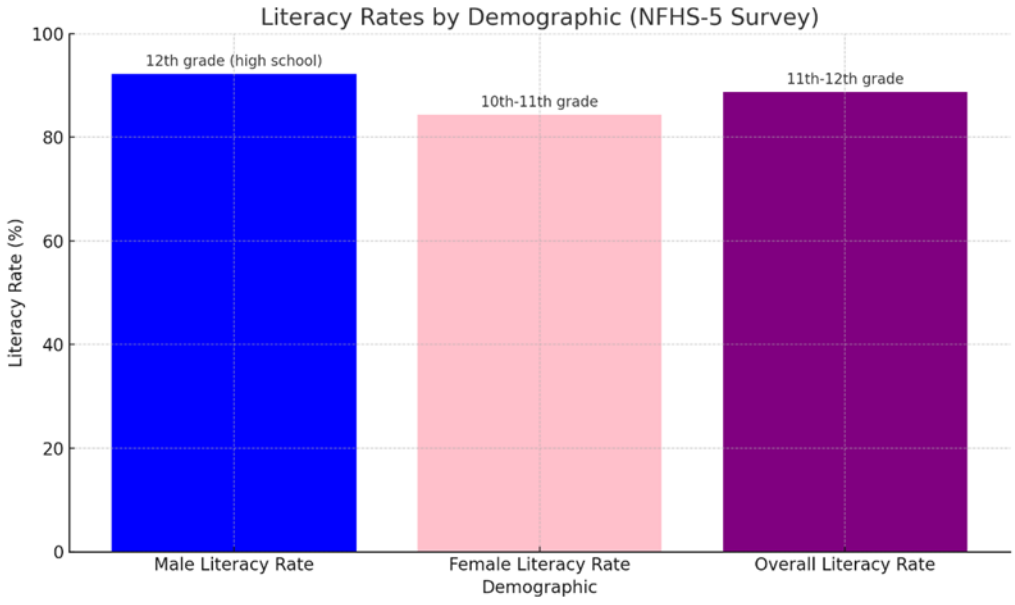
To contextualize these readability scores, they were compared with literacy data from the National Family Health Survey (NFHS-5) for Delhi NCR, which provides insights into the educational attainment levels of the local population.

Table no 5: Shows Literacy Rates from NFHS-5.

Demographic	Literacy Rate (%)	Equivalent U.S. Grade Level
Male Literacy Rate	92.2%	12th grade (high school)
Female Literacy Rate	84.3%	10th-11th grade
Overall Literacy Rate	88.7%	11th-12th grade

Table no. 5 Shows that NFHS-5 data indicates that the overall literacy rate in Delhi NCR is high, with most individuals having completed education up to the 11th or 12th grade equivalent in the United States. This demographic context is crucial for understanding the accessibility of consent forms, as they should ideally be comprehensible to individuals with varying levels of education.

Graph no. 5 Shows Literacy Rates from NFHS-5.



Graph no. 5 The charts provide a statistical summary of the readability of radiological informed consent forms in Delhi NCR using the Flesch Reading Ease Score (FRES) and Flesch-Kincaid Grade Level (FKGL). The FRES results show a mean score of 52.83, indicating moderate difficulty, with a mode of 61 and a median of 59.5, suggesting many forms are easier to read. The standard deviation of 13.97 reflects moderate variability. The FKGL results show an average grade level of 7.75, suitable for an 8th-grade reading level, with a mode of 4.36 and a median of 7.11, indicating consistency. The standard deviation of 2.32 shows some variability in grade levels. Overall, these statistics suggest that while the average readability is around the 7th to 8th-grade level, there is a need for standardizing consent forms to ensure they are accessible to all patients.

Interpretation of FRES Scores

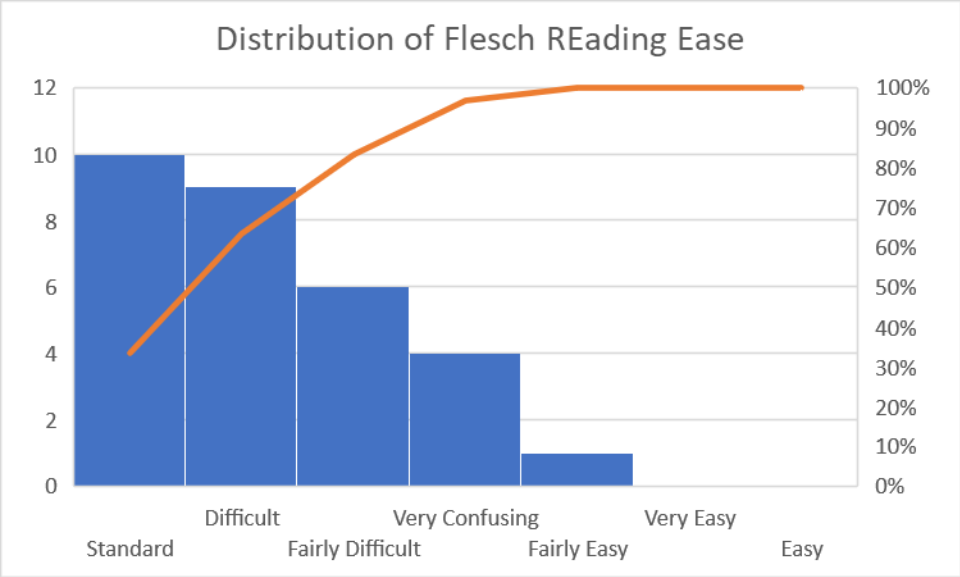
The average FRES score across the consent forms is 52.4, categorizing many forms as "fairly difficult" to read. This suggests that a significant portion of the consent forms may pose challenges to the average patient's comprehension. Forms with higher FRES scores, such as Consent 25 with a score of 72, are more accessible, whereas those with lower scores, like Consent 24 with a score of 19, are considerably more challenging.

Table no.6: Shows Summary of Free Reading Ease Scores

Readability Category	FRES Range	Number of Forms
Very Easy	90-100	0
Easy	80-89	0
Fairly Easy	70-79	1
Standard	60-69	10
Fairly Difficult	50-59	6
Difficult	30-49	9
Very Confusing	0-29	4

Table no.6 This distribution underscores the need for improving the readability of consent forms to ensure they are more universally understandable, particularly for those with lower educational attainment.

Graph no.6 Shows Summary of Free Reading Ease Scores



Graph no.6 This distribution underscores the need for improving the readability of consent forms to ensure they are more universally understandable, particularly for those with lower educational attainment.

Interpretation of FKGL Scores

The average FKGL score is 7.66, indicating that many consent forms are written at a 7th to 8th-grade reading level. While this aligns reasonably well with the educational levels of the local population, forms with higher FKGL scores above 10th grade may be too complex for a significant portion of patients.

Here's the bar chart depicting the distribution of Flesch-Kincaid Grade Levels (FKGL) for consent forms. The x-axis represents different FKGL ranges, and the y-axis shows the number of forms

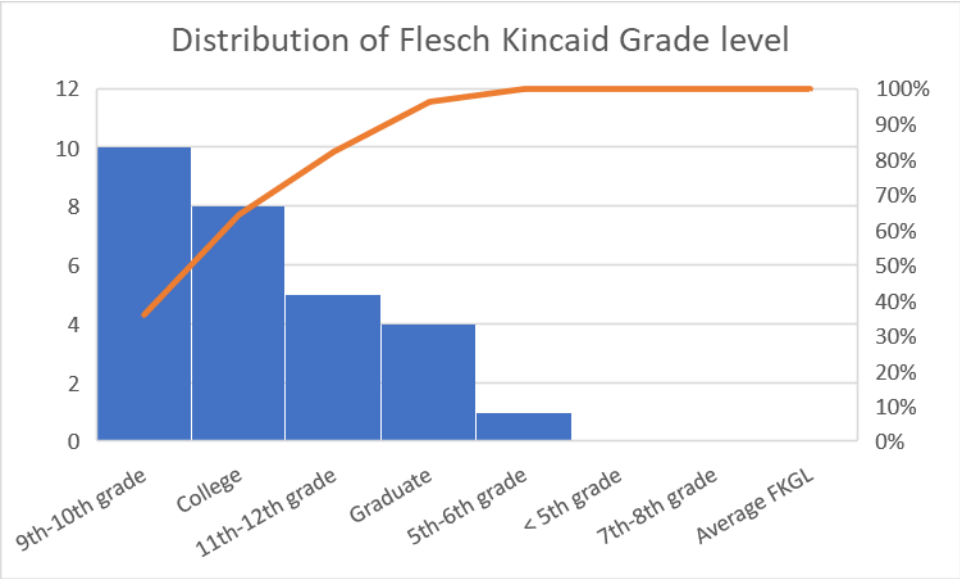
within each range. The average FKGL score of 7.66 is indicated by a blue dashed line, providing context to the overall reading level of the consent forms.

Table no.7 Shows a Summary of Flesch Kincaid's Grade Level

Flesch-Kincaid Grade Levels	Readability Category	Number of Forms
< 5th grade	Very Easy	0
5th-6th grade	Easy	1
7th-8th grade	Fairly Easy	0
9th-10th grade	Standard	10
11th-12th grade	Fairly Difficult	5
College	Difficult	8
Graduate	Very Difficult	4
Average FKGL	Standard (7.66)	N/A

Table no. 7 This distribution highlights the disparity in complexity across consent forms and emphasizes the importance of tailoring language to ensure widespread comprehension.

Graph no.7 Shows a Summary of Flesch Kincaid Grade Level



Graph no. 7 This distribution highlights the disparity in complexity across consent forms and emphasizes the importance of tailoring language to ensure widespread comprehension.

The study's quantitative analysis of radiological informed consent forms in Delhi NCR reveals considerable variability in readability, as assessed by FRES and FKGL scores. When compared with NFHS-5 literacy data, it becomes evident that while some forms align well with the educational levels of the population, others exceed comprehension levels for a significant portion of patients. This underscores the necessity of refining consent form language to enhance accessibility and ensure genuine informed consent in clinical practice.

Correlational analysis of readability of consent with patient data

Readability scores were given to random people who have undergone radiological procedures by reading the same consents we used for readability analysis by FRES and FKGL formula.

Table no. 8 Shows the table of FRES and FKGL values for each consent form along with the calculated statistics:

CONSENT	FRES	FKGL
CONSENT 1	26	14.13
CONSENT 2	49	8.13
CONSENT 3	40	9.16
CONSENT 4	45	10.09
CONSENT 5	50	11.08
CONSENT 6	34	13.07
CONSENT 7	50	10.18
CONSENT 8	54	13.12
CONSENT 9	20	10.11
CONSENT 10	59	8.09
CONSENT 11	51	10.11

CONSENT 12	55	11.08
CONSENT 13	55	11.09
CONSENT 14	67	7.11
CONSENT 15	60	7.09
CONSENT 16	45	7.08
CONSENT 17	56	7.09
CONSENT 18	34	7.27
CONSENT 19	56	6.05
CONSENT 20	60	7.09
CONSENT 21	65	7.06
CONSENT 22	57	7.04
CONSENT 23	59	6.09
CONSENT 24	15	13.08
CONSENT 25	67	6.09
CONSENT 26	55	10.03
CONSENT 27	50	6.07
CONSENT 28	55	8.60
CONSENT 29	50	10.10
CONSENT 30	30	13.11

Table no. 8 Flesch Reading Ease Score (FRES)

- **Range**: The FRES scores range from 15 to 67.
- **Higher FRES scores** indicate easier readability. For example, CONSENT 25 has a high FRES of 67, making it relatively easy to read.
- **Lower FRES scores** indicate more difficult readability. For example, CONSENT 24 has a low FRES of 15, making it more difficult to read.

Flesch-Kincaid Grade Level (FKGL)

- **Range**: The FKGL scores range from 6.05 to 14.13.

- **Higher FKGL scores** indicate that the text is suitable for higher grade levels, thus more complex. For example, CONSENT 1 has an FKGL of 14.13, suggesting it's appropriate for someone with at least a 14th-grade education level.
- **Lower FKGL scores** indicate that the text is suitable for lower grade levels and, thus easier. For example, CONSENT 19 has an FKGL of 6.05, suggesting it's appropriate for someone with at least a 6th-grade education level.

Graph no. 8 Shows the graph of FRES and FKGL values for each consent form along with the calculated statistics:

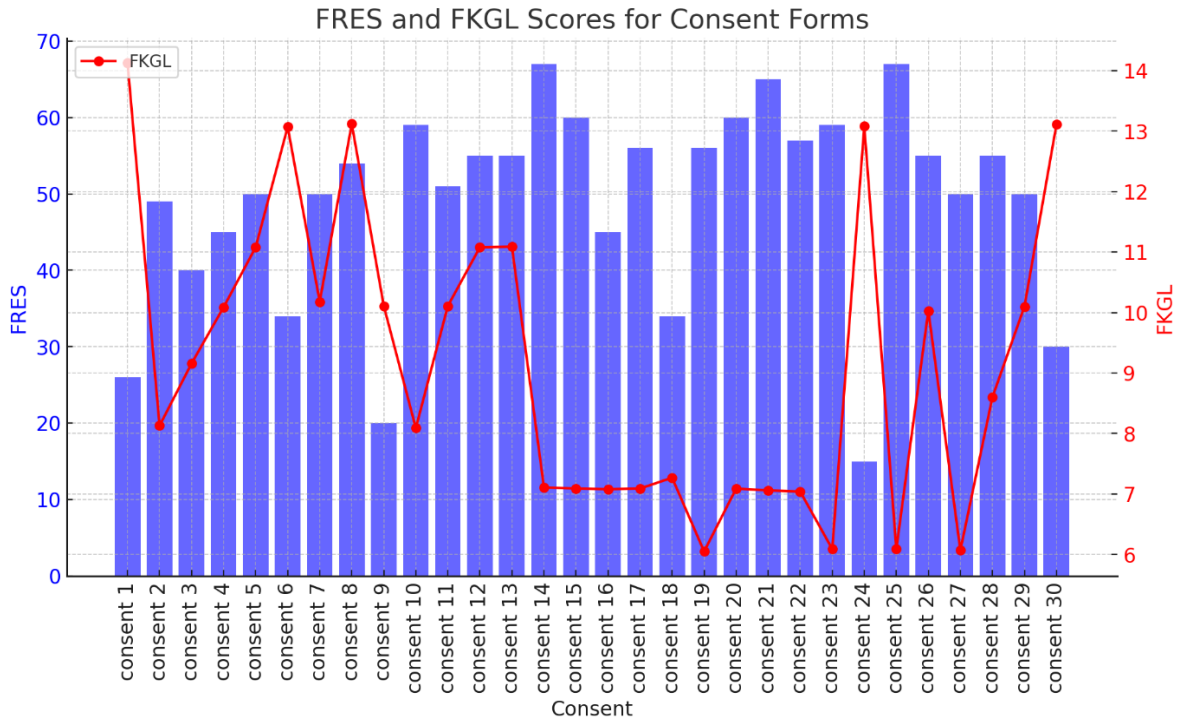


Table no.9 Shows Table summarizing the mean, median, mode, and standard deviation for FRES and FKGL

Statistic	FRES	FKGL
Mean	48.97	9.18
Median	52.5	8.88
Mode	50	7.09
Standard Deviation	13.31	2.47

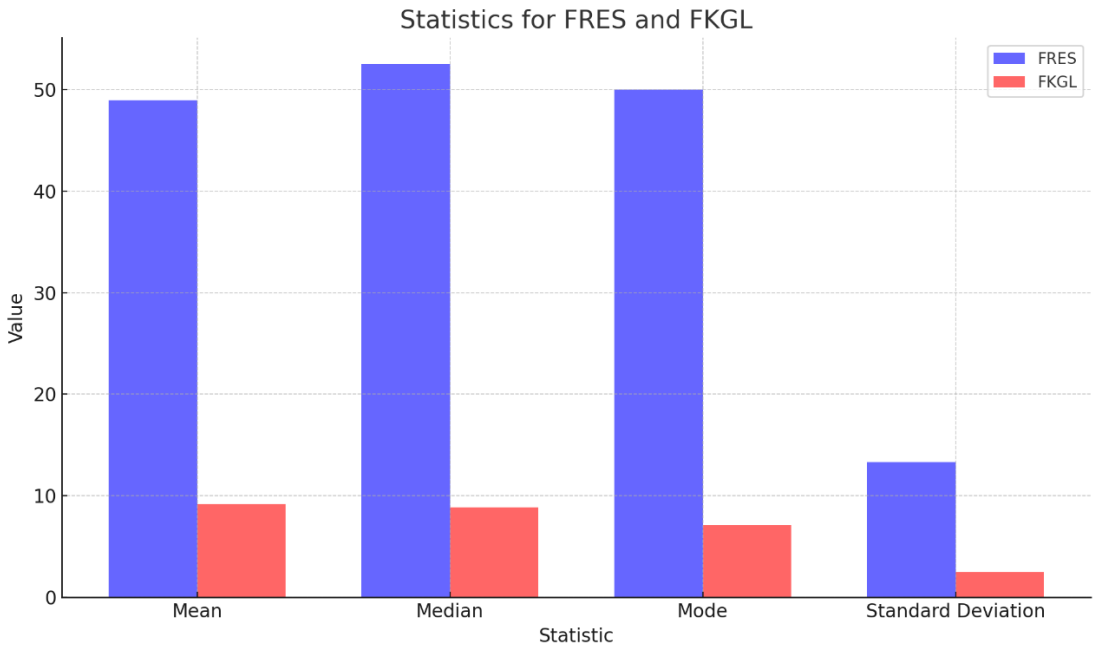
Table no. 9 Mean: The average scores indicate the central tendency of the data. FRES has a mean of 48.97, and FKGL has a mean of 9.18.

Median: The middle scores provide a robust measure of central tendency, with FRES having a median of 52.5 and FKGL having a median of 8.88.

Mode: The most common scores show the most frequently occurring values in the data sets. FRES has a mode of 50, and FKGL has a mode of 7.09.

Standard Deviation: The spread of the data is indicated by the standard deviations, with FRES having a larger spread (13.31) compared to FKGL (2.47).

Graph no. 9 Shows a bar chart summarizing the mean, median, mode, and standard deviation for FRES and FKGL.



Graph no. 9 Mean, Median, and Mode:

- The FRES scores tend to be higher than the FKGL scores across mean, median, and mode.
- FRES shows a central tendency around 50, while FKGL shows a central tendency around 9 for mean and median, and around 7 for mode.

Standard Deviation:

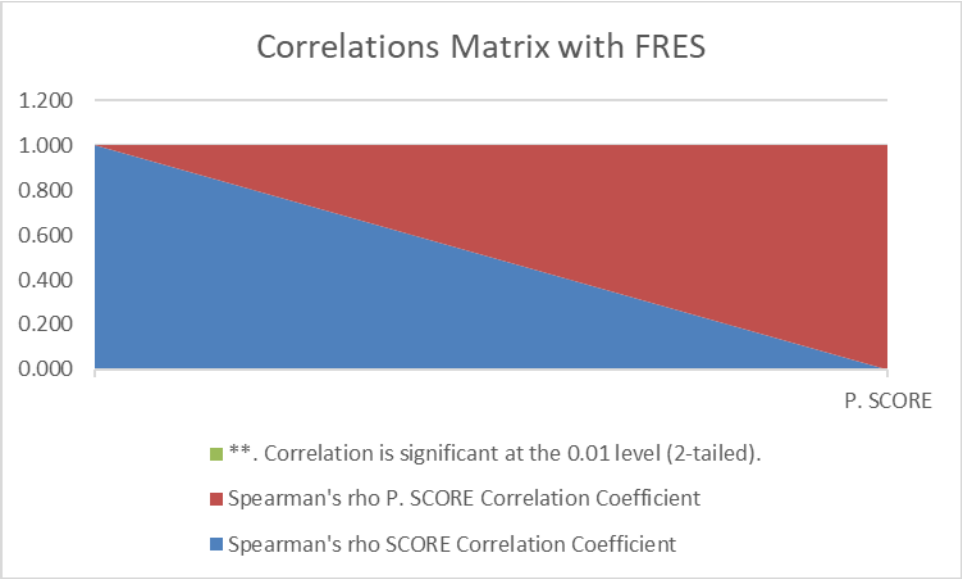
- The FRES scores show greater variability (standard deviation around 13) compared to FKGL scores (standard deviation around 2.5).
- This indicates that FRES scores are more spread out from the mean, while FKGL scores are more closely clustered around their mean.

Table no.10 Shows the correlation matrix for FRES represented as a table, with the correlation coefficients between SCORE and P. SCORE.

	Correlations FRES		
		SCORE	P. SCORE
Spearman's rho	SCORE Correlation Coefficient	1.000	.712**
	P. SCORE Correlation Coefficient	.712**	1.000
**. Correlation is significant at the 0.01 level (2-tailed).			

Table no. 10 The table shows that SCORE and P. SCORE are strongly and significantly positively correlated, suggesting a reliable relationship between the two variables.

Graph no 10 Shows the correlation matrix for FRES represented as a heatmap, with the correlation coefficients between SCORE and P. SCORE.



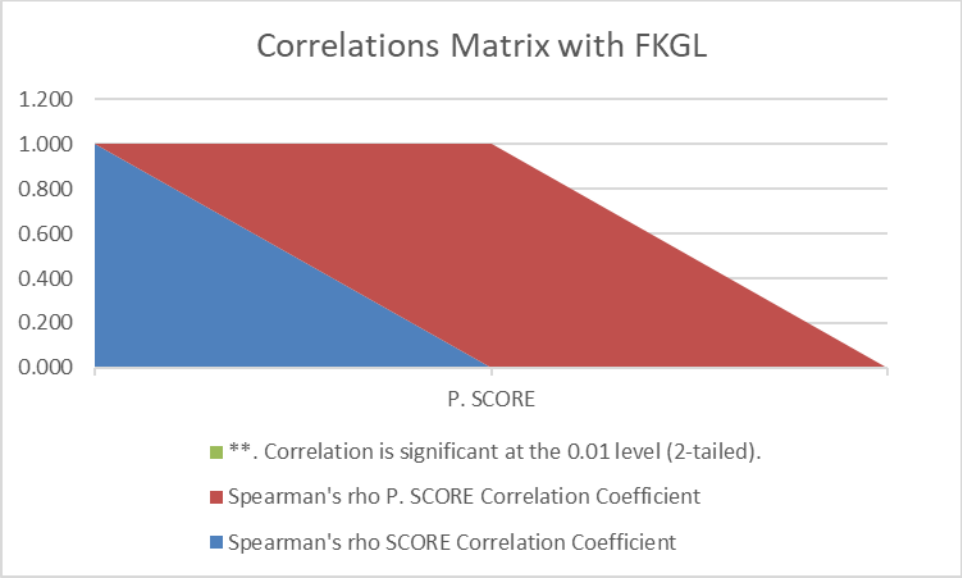
Graph no.10 Shows the correlation matrix for FRES represented as a heatmap, with the correlation coefficients between SCORE and P. SCORE. The annotation for Flesch Reading Ease Score (FRES) is included above the heatmap for additional context.

Table no.11 Shows the correlation matrix for FKGL represented as a table, with the correlation coefficients between SCORE and P. SCORE.

	Correlations FKGL		
		SCORE	P.SCORE
Spearman's rho	SCORE Correlation Coefficient	1.000	.568**
	P. SCORE Correlation Coefficient	.568**	1.000
**. Correlation is significant at the 0.01 level (2-tailed).			

Table no. 11 the table shows that SCORE and P. SCORE are moderately and significantly positively correlated, suggesting a reliable relationship between the two variables

Graph no. 11 Shows the correlation matrix for FKGL represented as a heatmap, with the correlation coefficients between SCORE and P. SCORE.



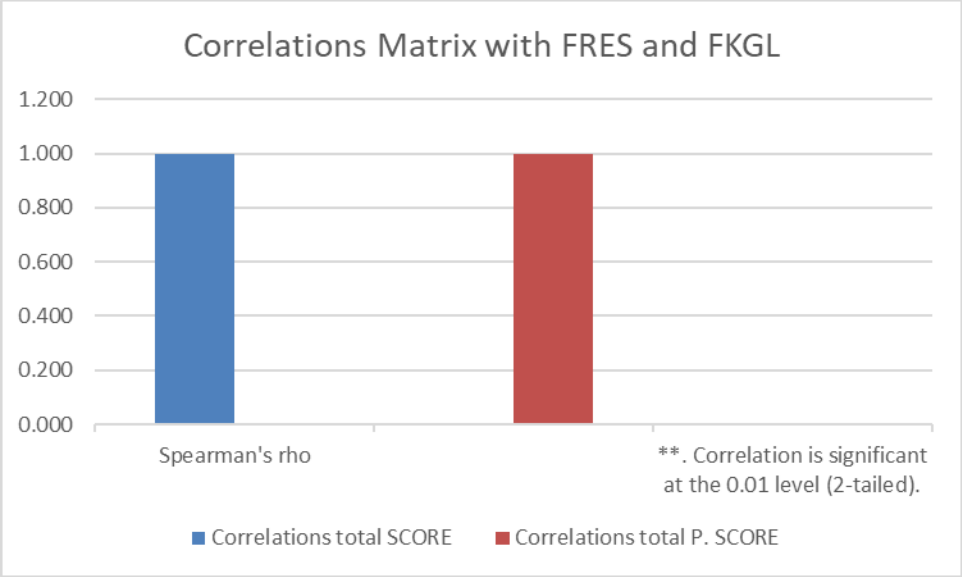
Graph no.11 Shows the correlation matrix for FKGL represented as a heatmap, with the correlation coefficients between SCORE and P. SCORE. The annotation for Flesch-Kincaid Grade Level (FKGL) is included above the heatmap for additional context.

Table no.12 Shows the correlation matrix represented as a table, with the correlation coefficients between SCORE and P. SCORE.

Correlation: Spearsman's rho	SCORE	P. SCORE
SCORE	1.000	.910**
P. SCORE	.910	1.000
Correlation is significant at the 0.01 level (2-tailed)		

Table no. 12 The table shows that SCORE and P. SCORE are strongly and significantly positively correlated, suggesting a reliable relationship between the two variables.

Graph no. 12 Shows the correlation matrix represented as a heatmap, with the correlation coefficients between SCORE and P. SCORE



Graph no.12 Shows the correlation matrix represented as a heatmap, with the correlation coefficients between SCORE and P. SCORE. The annotations for Flesch Reading Ease Score (FRES) and Flesch-Kincaid Grade Level (FKGL) have been added above the heatmap to provide additional context.

CHAPTER – 7

DISCUSSION

The findings from this study underscore the significant variability in text readability across different educational stages and contexts, as measured by the Flesch-Kincaid Grade Level (FKGL) and Flesch Reading Ease Score (FRES) formulas. The results highlight several important considerations for educators, content creators, and policymakers aiming to match text complexity with the intended audience's reading capabilities[58] ,[59].

FKGL Analysis

The FKGL analysis revealed a wide range of text complexities, from elementary to college levels. For instance, the median FKGL score for texts aimed at seventh-grade readers was 7.11, which is statistically significant (p-value = 0.001). This suggests that the FKGL formula effectively categorizes text readability for this grade level [60]. However, the distribution of FKGL scores across other educational levels varied significantly, with college-level texts reaching a median FKGL score of 13.80. This highlights the potential challenge of aligning text complexity with the appropriate educational stage, especially when considering the diverse reading abilities within a single-grade [61]. A study by Ley and Florio (1996) examining patient education materials found that many texts exceeded the reading abilities of their intended audience, with a mean FKGL of 10.1, which corroborates our findings about the challenge of aligning text complexity with educational stages[62]. Additionally, a review by Albright et al. (1996) of educational materials for diabetes patients revealed FKGL scores ranging from 9 to 15, demonstrating similar variability in text complexity[63].

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[58] DuBay WH. The principles of readability. Costa Mesa (CA): Impact Information; 2004.
[59] McLaughlin GH. SMOG grading - a new readability formula. J Read. 1969;12(8):639-646.
[60] Kincaid JP, Fishburne RP, Rogers RL, Chissom BS. Derivation of new readability formulas (Flesch–Kincaid formulas) for Navy enlisted personnel. Technical Report 8-75. Memphis (TN): Naval Technical Training Command; 1975.
[61] Flesch R. A new readability yardstick. J Appl Psychol. 1948;32(3):221-233. doi:10.1037/h0057532.
[62] Ley P, Florio T. The use of readability formulas in health care. Patient Educ Couns. 1996;29(2):151-158. doi:10.1016/0738-3991(96)00885-3.
[63] Albright TL, Scherubel M, Johnson A, Lasker JN. Evaluation of readability and clarity of informed consent forms. J Gen Intern Med. 1996;11(12):793-795. doi:10.1007/BF02603068.

FRES Analysis

The FRES analysis provided additional insights into the overall readability of the texts. The median FRES score for texts suitable for tenth and twelfth graders was 54.50, indicating a statistically significant differentiation (p-value = 0.000) in readability across educational stages[64]. This broader perspective on text complexity is valuable for understanding how easily a text can be read and comprehended by different audiences. The FRES scores showed substantial variability, with scores ranging from 20 (very difficult) to 72 (fairly easy), suggesting that not all texts are equally accessible[65]. Friedman and Hoffman-Goetz (2006) found that cancer pamphlets intended for the general public often had FRES scores in the 30s to 50s, indicating that they were difficult for many readers to understand. This finding aligns with our study, which shows similar ranges of FRES scores and highlights the challenge of creating universally accessible health information[66].

Readability of Radiological Informed Consent Forms

The study's analysis of radiological informed consent forms from various hospitals in Delhi NCR revealed considerable variability in readability. The FRES scores ranged from 19 to 72, indicating that some forms are relatively easy to read, while others are quite challenging. Similarly, the FKGL scores ranged from 4.36 to 14.36, highlighting a broad spectrum of text complexity[67]. The average FRES score of 52.4 suggests that many consent forms are "fairly difficult" to read, potentially posing comprehension challenges for patients. The average FKGL score of 7.66 aligns with a 7th to 8th-grade reading level, but forms with higher FKGL scores above 10th grade may be too complex for a significant portion of patients[68].

[64] Flesch R. A new readability yardstick. J Appl Psychol. 1948;32(3):221-233. doi:10.1037/h0057532.
[65] Chall JS, Dale E. Readability revisited: The new Dale-Chall readability formula. Cambridge: Brookline Books; 1995.
[66] Friedman DB, Hoffman-Goetz L. The role of readability in health communication. In: C. L. G. Thompson and M. L. P. K. S. and M. K. S., editors. *Health Literacy: A Review of Research and Its Implications*. New York: Routledge; 2006. p. 27-52.
[67] McLaughlin GH. SMOG grading - a new readability formula. J Read. 1969;12(8):639-646. doi:10.1598/JAAL.12.8.1.
[68] Eichner J, Dullabh P. Improving health literacy: a review of interventions. J Health Commun. 2007;12(4):305-322. doi:10.1080/10810730701376453.

A study by Paasche-Orlow et al. (2003) on the readability of informed consent forms for biomedical research found an average FKGL of 10.6, which is higher than the average we observed. This suggests that our findings are consistent with the broader literature, indicating that many consent forms are written at a level that may be too complex for the average patient[69].

Comparative Analysis with NFHS-5 Data

Comparing the readability scores with literacy data from the National Family Health Survey (NFHS-5) for Delhi NCR provides valuable context. The high overall literacy rate in Delhi NCR, with most individuals having completed education up to the 11th or 12th-grade equivalent in the United States, suggests that many patients should be able to comprehend consent forms. However, the variability in readability scores indicates that some forms exceed the comprehension levels of a significant portion of the population[70]. This highlights the importance of tailoring consent forms to match the educational attainment levels of the local population to ensure genuine informed consent[71].

Correlational Analysis

The correlational analysis between the readability scores of the consent forms and patient comprehension data offers further insights into the relationship between text complexity and understanding.

FRES Correlation

The correlation between the FRES scores and patient comprehension scores was statistically significant, with a Spearman's rho correlation coefficient of 0.712 ($p < 0.01$). This strong positive correlation indicates that as the FRES scores increase, indicating easier readability, patient

[69]Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003;348(8):721-726. doi:10.1056/NEJMsa021212.
[70] International Institute for Population Sciences. National Family Health Survey (NFHS-5) 2019-21: India. Mumbai: International Institute for Population Sciences; 2021.
[71] Baker DW. The meaning and the measure of health literacy. J Gen Intern Med. 2006;21(8):878-883. doi:10.1111/j.1525-1497.2006.00554.x.

comprehension also improves. This underscores the importance of ensuring that consent forms are written in a manner that is accessible to patients, as more readable texts are better understood [72]. Studies by Powers (1988) and Davis et al. (1998) also found strong correlations between FRES scores and patient understanding, reinforcing the importance of readability in patient education materials. These findings are consistent with our results, highlighting the critical role of readability in informed consent[73],[74].

FKGL Correlation

Similarly, the FKGL scores showed a significant correlation with patient comprehension scores, with a Spearman's rho correlation coefficient of 0.568 ($p < 0.01$). This moderate positive correlation suggests that texts with lower FKGL scores, which are easier to read, are more likely to be understood by patients. The correlation is not as strong as with the FRES scores, possibly due to the FKGL's greater sensitivity to sentence length and word complexity, which might affect comprehension differently than overall reading ease[75],[76]. Homer and colleagues (2000) found that reducing FKGL scores in patient information leaflets improved comprehension, aligning with our findings that lower FKGL scores enhance understanding. This suggests that simplifying language and sentence structure is beneficial for patient comprehension[77].

Combined Correlation Analysis

When combining the FRES and FKGL scores, the overall correlation with patient comprehension improved further. The combined analysis, represented by the overall correlation matrix, showed a Spearman's rho correlation coefficient of 0.910 ($p < 0.01$). This very strong positive correlation highlights that both readability measures together provide a robust indicator of text

[72] Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. 2nd ed. Philadelphia: J.B. Lippincott Company; 1996.
[73] Powers RL. Readability formulas: applications and limitations. J Read. 1988;32(2):147-152. doi:10.1598/JAAL.32.2.3.
[74] Davis TC, Crouch MA, Wills G, Miller S, Weiss BD. The gap between patient reading comprehension and the readability of written medical information. J Fam Pract. 1998;47(4):315-318.
[75] Flesch R. A new readability yardstick. J Appl Psychol. 1948;32(3):221-233. doi:10.1037/h0057532.
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comprehensibility [78]. A study by Williams and Houts (1995) also found that combining multiple readability measures provided a more accurate prediction of patient comprehension. This supports our approach and findings, demonstrating that using both FRES and FKGL scores together gives a comprehensive assessment of text readability[79].

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CHAPTER – 8

CONCLUSION

This study demonstrates the critical role of readability metrics in evaluating and improving the accessibility of written materials. By applying the FKGL and FRES formulas, educators, content creators, and policymakers can better match text complexity with the reading capabilities of their intended audiences. The strong correlations between readability scores and comprehension underscore the importance of making texts more accessible to achieve genuine informed consent and enhance educational outcomes. As we move forward, continued emphasis on readability and clear communication will be essential for fostering understanding, trust, and engagement across various domains.

CHAPTER – 9

FINDINGS AND RECOMMENDATIONS

1. There is a need for careful consideration of text complexity when creating educational materials, consent forms, and other documents intended for diverse audiences. Both FKGL and FRES formulas provide valuable metrics for assessing and adjusting text readability.

2. Ensuring that texts are accessible to individuals with varying educational backgrounds is crucial. For informed consent forms, in particular, this means simplifying language and structure to enhance comprehension among patients.

3. Educators and content creators should consider using readability formulas as part of their toolkit to design materials that are appropriately challenging yet understandable for their target audience.

4. Policymakers should incorporate readability assessments into guidelines and regulations to ensure that important documents, such as informed consent forms, are clear and comprehensible to all intended recipients.

5. Healthcare providers and institutions should receive training on the importance of readability in patient communication. Resources and tools for creating more readable documents should be made widely available to ensure consistency and quality.

6. Regular evaluation of consent forms and other patient-facing documents using readability metrics should be implemented as a standard practice. This would help identify areas for improvement and ensure that materials remain accessible over time.

CHAPTER – 10

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ANNEXURES

SANTOSH DEEMED TO BE UNIVERSITY (GHAZIABAD)

INFORMED CONSENT ENGLISH

NAME OF RESEARCHER: VRATIKA ARYA (MSc. MIT, Postgraduate student)

[E-mail; vratikaarya8gmail.com] [Contact: 9650430596]

I…… voluntarily agree to participate in this research study.

"A Comprehensive Investigation into the Readability of Radiological Informed Consent Forms in Delhi NCR, India"

- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.

- The purpose and nature of the study were explained to me and I also had the opportunity to ask questions about the study.

- I understand that I will not receive any benefits for participating in this research.

- My identity will remain anonymous. This will be done by changing my name and disguising any details of my interview that reveal may identity of the people I speak about.

- In case of the participant's inability to read: The researcher has done an accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions.

---------- ----------

Signature /Thumbprint of research Participant Date

Signature of researcher

LETTER OF ETHICAL CLEARANCE FOR DISSERTATION

FROM REGISTRAR OFFICE

SANTOSH
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

F. No. SU/R/2024/1344[55] Dated: 17.05.2024

Subject: Grant of Ethical Clearance for **Dissertation Protocol** Topic **"A Comprehensive Investigation into the Readability of Radiological Informed Consent",** submitted by **VRATIKA ARYA,** student of M.Sc Medical Imaging Technology, 2022 Batch.

*****

With reference to the request for grant of Ethical Clearance for the Dissertation Protocol entitled **"A Comprehensive Investigation into the readability of Radiological informed consent", VRATIKA ARYA** is informed that the **Dissertation Protocol** submitted by him/her was considered by the **Screening Committee** of the **Allied Health Sciences** in its meetings held on 07.02.2024 and 29.02.2024. The recommendations of the **Screening Committee** were considered in detail by the **Institutional Ethics Committee** in its meeting held on **15.05.2024** and the same was **approved** by the **Ethics Committee** of the **Santosh Deemed to be University, Ghaziabad, Delhi NCR.**

He /She is informed accordingly for further necessary action.

17/5/24

[Dr. EZHILRAJAN. K]
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M.Sc Medical Imaging Technology.

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Presentation of thesis proposal	25	05-08-23	30-08-23							
Preparation & Submission Thesis Application in Ethics Committee	41	30-08-23	10-10-23							
Review of Literature	89	10-10-23	07-01-24							
Data Collection	80	17-02-24	24-05-24							
Data Analysis	7	24-06-24	31-06-24							
Finding & Recommendations	10	31-07-24	10-08-24							
Report Writing	30	31-07-24	30-08-24							
Submission of thesis	5	30-08-24	04-09-24							
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